and were not referenced in documents that were circulated to the Commission;

(2) Transcripts or audio tapes of Commission discussions that are pre-decisional, but such transcripts or tapes may be made available under 11 CFR Parts 4 or 5; or

(3) Documents properly subject to privileges such as an attorney-client privilege, or items constituting attorney work product.

(c) The administrative record identified in paragraph (a) of this section is the exclusive record for the Commission's determinations under 11 CFR Part 9033 and §§ 9034.5, 9036.5 and 9038.2.

Dated: September 30, 1994.

Trevor Potter,

Chairman.

[FR Doc. 94-24623 Filed 10-5-94; 8:45 am]

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101 et al.

Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 170, and 310

[Docket Nos. 91P–0186 and 93P–0306]

Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations to require label warning statements for products taken in solid oral dosage form to supplement the dietary intake of iron or to provide iron for therapeutic purposes. FDA is also proposing regulations to require unit-dose packaging [1] for iron-containing products that contain 30 milligrams (mg) or more of iron per dosage unit.[2] FDA is proposing these regulations because of the acute iron poisonings, including deaths in children less than 6 years of age, attributable to accidental overdoses of iron-containing products. The intent of these proposed regulations is to reduce the risk of accidental iron poisonings of young children by utilizing FDA's authority in conjunction with the existing requirements of the U.S. Consumer Product Safety Commission (CPSC) for child-resistant packaging for household substances. This proposal responds to three citizen petitions (Docket Nos. 91P–0186/CP1, 93P–0306/CP1, and 93–0306/CP2) that requested that FDA take action to ensure that products containing iron or iron salts do not pose a health hazard to young children and infants.

DATES: Written comments by December 20, 1994. The agency is proposing that any final rule that may be issued based upon this proposal become effective 180 days after its publication in the **Federal Register.**

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John N. Hathcock, Center for Food Safety and Applied Nutrition (HFS–465), Food and Drug Administration, 8301 Muirkirk Rd., Laurel, MD 20708, 301–594–6006.

SUPPLEMENTARY INFORMATION:

I. Background

Iron is an essential nutrient that, in certain circumstances, can be toxic. For some women of child-bearing age and for some young children, iron from dietary sources alone may be insufficient to meet their metabolic iron requirements. Access to products that provide iron is useful for these groups to ensure that their iron requirements are met. However, when consumed acutely in large quantities by young children, iron is toxic and can, in some cases, lead to death.

Since the mid 1980's, an upsurge in reported accidental pediatric ingestion of iron-containing products has occurred (Ref.1). This fact, and the many resultant injuries and deaths of children, have created a dilemma with respect to how to ensure that iron sources are available while still minimizing the risks to children. In response, FDA is proposing regulations that require that a warning be placed on labeling about the adverse effects of acute, high dose iron ingestion by children and that unit-dose packaging be used for certain iron-containing products. These requirements, if adopted, will apply to iron-containing products in addition to the existing requirements of CPSC, which provide that child-resistant packaging must be used for most iron-containing products available (see section II.B. of this document). The agency tentatively finds that the effect of these new requirements, in conjunction with those of CPSC, will be to significantly reduce the risk of accidental pediatric iron poisoning.

The types of iron-containing products that have been associated with poisonings of young children are those offered in solid oral dosage form (e.g., capsules and tablets) as: (1) Children's and adult's multi-vitamin/mineral supplements that contain iron or iron salts (these products typically provide less than 30 mg of iron per dosage unit), (2) products intended for use as iron supplements (these products typically contain 30 mg or more of iron per dosage unit), and (3) drug products that contain iron or iron salts (these products typically contain 30 mg or more of iron per dosage unit). In this document, the term "iron-containing products" refers to all of these types of products.

The agency is not aware of incidents of poisoning being caused by iron-containing products in liquid or powder form. Therefore, these products are not subject to this proposal. The agency will consider what regulatory action is appropriate to take with regard to iron-containing products in liquid or powder form if it becomes aware of information indicating that these products have caused or can cause poisonings in children.

This document also does not bear in any way on conventional foods containing naturally occurring or added iron. Pediatric iron poisoning from consumption of iron-containing foods in conventional food form is unlikely because of limitations inherent in the large quantity of food that would have to be ingested to cause an adverse effect in young children. For example, a serving of a highly fortified breakfast cereal that contains 100 percent of the recommended daily intake for iron of 18 mg, would provide only 7 percent of the amount of iron that is considered necessary to produce symptoms of iron poisoning in a 10 kilograms (kg) (22 pounds (lb)) child (i.e., 25 milligrams (mg) per (/) kg of iron, which equates to 250 mg total iron for a 10 kg (22 lb) child. (See section I.B. of this document.) Moreover, the agency is not aware of any pediatric iron poisonings that have resulted from ingestion of iron-containing foods in conventional food form.

A. The Iron Requirements of Children and Women of Childbearing Age

Iron is an essential nutrient because it is a component of blood and muscle tissue and because of its role in metabolic reactions. Iron-containing compounds in the body may be grouped into two categories: (1) Those that serve metabolic functions, and (2) those associated with iron storage. The compounds in the first category include hemoglobin (a component of red blood cells), myoglobin (a muscle protein), and iron-containing enzymes. They account for approximately 80 percent of body iron. Compounds in the second category are involved in the maintenance of iron homeostasis and include the storage compounds ferritin and hemosiderin.

When the supply of dietary iron becomes inadequate to meet the body's needs, iron is mobilized from iron stores to maintain the production of red blood cells and to perform other essential iron-dependent functions. When body iron stores are low or depleted, as often occurs in women of child-bearing age

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[1] For the purposes of this document "unit-dose packaging" means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units.

[2] In this document, the term "dosage unit" will be used to denote the individual physical units of the iron-containing product such as tablets, capsules, caplets, or other physical forms, irrespective of whether one or more than one of these physical units comprises the recommended dose.

and in very young children, a person is vulnerable to adverse effects associated with iron deficiency anemia and with a reduction in metabolic and body functions.

Although the prevalence of iron deficiency in the U.S. population is low (Ref. 2), maintenance of adequate iron stores in women of childbearing age and in young children is an important public health issue. A woman's recommended daily allowance (RDA) for iron during pregnancy doubles from 15 to 30 mg/day (Ref. 3). The importance of prenatal iron supplementation in preventing depletion of iron stores in pregnant women has been shown in several clinical trials (Ref. 4). Thus, pregnant women are often counseled to increase their iron intake through dietary changes and the use of iron-containing supplements or drugs.

A committee of the National Academy of Sciences (NAS) has recommended that all pregnant women should be screened for iron deficiency anemia at the first prenatal visit and at least once during each subsequent trimester (Ref. 5). The NAS committee recommended, however, that iron supplementation should only be given when iron status is low or marginal, as indicated by hemoglobin and serum ferritin, in comparison with standard values recommended by NAS for the specific trimester of pregnancy. When these clinical indicators reveal deficient iron status, the NAS committee recommended that the clinician prescribe 60 to 120 mg of supplemental iron per day. If iron status is marginal, the NAS committee recommended that the clinician prescribe 30 mg of supplemental iron per day. If iron status is normal, the NAS committee recommended that these be no iron supplementation.

Aside from the iron needs that arise during pregnancy, women of child-bearing age have a higher requirement for iron than other adults. (The RDA for women of child-bearing age is 15 mg/day because of the depletion of iron through menstrual blood loss. It is 10 mg/day for adult males and older adult women (Ref. 3).) The difficulty of obtaining dietary intakes high enough to replace those losses through consumption of a normal diet is responsible for iron deficiency in some women of child-bearing age. For these women also, the use of iron-containing products may be prudent.

Iron deficiency also affects young children (the RDA for iron for children is 10 mg/day), particularly during the rapid growth period from 6 months to 4 years of age. Some young children fail to develop adequate iron stores to supply the iron needed for their metabolic functions during this early growth period. Data from the National Health and Nutrition Examination Survey (NHANES II) for children show that the prevalence of impaired iron status ranges from an estimated 3 to 12 percent (Ref. 2). Thus, iron supplementation may also be indicated in children whose iron needs are not met through dietary intake.

B. Iron Toxicity in Young Children

Although the minimal toxic and lethal doses for iron have not been clearly established (Ref. 6), the severity of iron poisoning when an overdose has been ingested is related to the amount of iron absorbed into the circulatory system. Experts have stated that ingestion of 25 mg/kg of iron (250 mg total iron for a 10 kg child) may produce symptoms of poisoning, and that ingestion of 60 mg/kg total iron for a 10 kg child is the minimum intake for the development of significant iron poisoning (Refs. 6 and 7). One source recommends emergency room evaluation when ingestion of iron exceeds 50 mg/kg (Ref. 6). An acute ingestion of more than 250 mg/kg for a 10 kg child is typically considered a lethal dose for iron (Ref. 8). However, it has been reported that ingestion of 100 to 200 mg/kg for a 10 kg child can be fatal (Ref. 9), and that ingestion of as little as 650 mg of iron (65 mg/kg for a 10 kg child) has resulted in death (Ref. 7). Based upon these reported values, acute ingestions of less than 1,000 mg of iron appear to be likely to cause nonfatal injuries of varying severity, depending on the amount of ingested iron.

Iron overdose results in both local and systemic effects (Ref 10). Toxicity is caused by both a direct corrosive effect on the gastrointestinal mucosa and the presence of unbound iron in the circulatory system. Locally in the stomach and intestine, ingested iron is corrosive and produces death of cells in the mucosa lining the gastrointestinal tract, resulting in ulceration and hemorrhage. While intact mucosa limits the absorption of iron, eroded mucosa permits absorption of relatively huge amounts of iron into the portal circulation that goes immediately to the liver, causing damage to liver cells. Overload of the liver cells, which normally remove iron from the circulation, allows iron to enter the general circulation.

When the circulating iron exceeds the capacity of certain proteins to bind it, free iron reaches other tissues, such as kidneys, lungs, heart and blood vessels, and the brain. The resultant death of cells in these tissues produces the following wide-spread symptoms and signs of iron poisoning: Kidney failure, edema in the lung, hemorrhage, hypotension from damage to the heart and blood vessels, coma from damage to the brain, and acidosis from release of organic acids.

Severe iron poisoning is characterized by four clinical stages (Refs. 6 and 9):

(1) Stage one, which may occur within 30 minutes (min) of ingestion, is characterized primarily by signs and symptoms of hemorrhagic gastroenteritis (i.e., nausea, vomiting, abdominal pain, hematemesis (vomiting blood), and bloody diarrhea) that may progress to shock, coma, seizures, and death.

(2) During stage two, which occurs from 2 to 12 hours (hr) after ingestion, patients may be without symptoms and may appear to have recovered. Some children will recover, but some may progress to stage three. The appearance of recovery should not delay evaluation and treatment for iron poisoning because successful treatment is difficult once the iron is absorbed from the small intestine into the blood.

(3) During stage three, from 12 to 48 hr after ingestion, there is a recurrence of gastrointestinal hemorrhage with severe lethargy or coma, and there may be liver and kidney failure and collapse of the heart and blood vessels.

(4) Stage four, 3 to 4 weeks after survivors of poisonings ingested the iron, may include gastrointestinal obstruction and cirrhosis of the liver.

In evaluating a child who is thought to have ingested an overdose of iron, an abdominal x-ray looking for iron-containing tablets, a qualitative color test for iron in the stomach contents, and an emergency determination of the concentration of iron in blood plasma may be performed.

If an overdose of iron is indicated, an emetic agent may be administered to cause regurgitation of the iron if the patient is fully awake and alert. In addition to emesis, catharsis with saline or sorbitol may be used to induce gastric emptying. However, neither emesis nor catharsis is advised if hemorrhagic gastroenteritis is present. Gastric lavage, i.e., washing out of the stomach, with saline or sodium bicarbonate or whole bowel irrigation with a balanced polyethylene glycol-electrolyte solution by gastric tube have been used to remove undissolved tablets (Ref. 11).

Treatment for an iron overdose frequently includes parenteral administration of deferoxamine (also referred to as desferrioxamine), a drug which chelates (i.e., binds) iron in the intracellular fluid and causes its

excretion in urine (Ref. 6). Given that 1 g deferoxamine can bind 93 mg of iron, and that, to avoid hypotension, infusion is generally recommended at 15 mg/kg/hr, there is a limit to the amount of iron deferoxamine can bind. For example, safe administration of deferoxamine to a 10 kg child over a 24 hr period is capable of binding only 324 mg of iron (Refs. 11 and 12).

Therefore, if very high levels of iron are absorbed, even prompt treatment with deferoxamine or another agent may not prevent a fatal outcome if chelation at the maximum safe rate cannot reduce the iron burden to levels below those that cause death.

Speed of diagnosis and therapy are important. With earlier and more effective treatment, the mortality rate from iron poisoning has been reduced from as high as 45 percent to about 1 percent (Ref. 9).

C. Summary of Information on Pediatric Deaths and Injuries

1. Citizen Petitions

Data have been submitted to or obtained by FDA on reports of deaths attributable to accidental pediatric iron poisoning that were made between 1983 and 1993 to the American Association of Poison Control Centers and between 1986 and 1993 to CPSC (Table 1). Although these two sets of data are not identical, they do have extensive overlap (cases included in both databases). They both point to an increase in reported fatalities from accidental iron poisonings of children in the early 1990's.

The number or rate of fatalities does not represent the totality of the health hazard, however. Data obtained by FDA from the American Association of Poison Control Centers (AAPCC) show that from 1986 through 1992 there were nearly 63,000 reports to poison control centers involving ingestion of adult iron- containing products, with over 47,000 of these reports involving children under 6 years of age (Refs. 14 through 20). Many of these victims required hospitalization, and many others required some medical treatment. For example, Table 2 shows that over 1,500 of these cases were classified as having "moderate outcomes," i.e., the patient had symptoms that, while not life threatening, usually required some form of treatment. One hundred fifty-nine cases were classified as "major outcomes," i.e., they were life threatening or resulted in permanent injury. Except for 1992, AAPCC data do not indicate how many of the moderate and major outcomes involved children under 6 years of age. However, for 1992, 55 percent (17/31) of the major outcomes, and 51 percent (141/278) of the moderate outcomes, involved children under 6 years of age.

TABLE 1.—IRON POISONING DEATHS FOR CHILDREN UNDER SIX

Year	Number of deaths reported to CPSC from 1986–1993	Number of deaths reported to AAPCC from 1983–1993 [1]
1993	[2] 1	3
1992	9	7
1991	11	11
1990	7	5
1989	3	2
1988	5	3
1987	3	1
1986	4	1
1985		1
1984		1
1983		2

[1] Data through 1991 were taken from the AAPCC petition. Data for 1992 and 1993 were taken from AAPCC annual reports.

[2] Data through August 1993 (partial year) were taken from the Attorneys General petition.

TABLE 2.—OUTCOMES OF INGESTIONS OF ADULT IRON-CONTAINING PRODUCTS REPORTED TO POISON CONTROL CENTERS FROM 1986–1992 [1]

Year	Total ingestions for all ages [2]	Outcomes for total ingestions [3]	
		Moderate	Major
1992	11,007	278	31
1991	10,671	276	26
1990	9,550	229	28
1989	9,734	194	22
1988	9,201	245	15
1987	7,132	153	20
1986	5,674	144	17
Total	62,969	1,519	159

[1] Products included for the 1989–1992 data are iron-containing supplements and drug products and adult multiple vitamin tablets with iron. Products included for the 1986–1988 data are iron-containing supplements and drug products and adult multivitamin type supplements of unspecified dosage form. Some of the products also contained fluoride.

[2] 47,690 of this total involved children under 6 years of age.

[3] Only the 1992 data report moderate and major outcomes for children under 6 years of age. In 1992, 141 such moderate outcomes and 17 major outcomes were reported.

In addition, AAPCC data show that during the same 7-year period, there were over 76,000 reports to poison control centers involving ingestion of pediatric iron-containing products with over 69,000 of these reports involving children under 6 years of age (Refs. 14 through 20). Table 3 shows that over 495 of these cases were classified as having "moderate outcomes," and 29 cases were classified as "major outcomes." Again, except for 1992, AAPCC data do not indicate how many of the moderate and major outcomes involved children under 6 years of age. However, for 1992, the single major outcome, and 91 percent (52/57) of the moderate outcomes, involved children under 6 years of age.

TABLE 3.—OUTCOMES OF INGESTION OF PEDIATRIC IRON-CONTAINING PRODUCTS REPORTED TO POISON CONTROL CENTERS FROM 1986–1992 [1]

Year	Total ingestions for all ages	Less than 6 years of age	Outcomes for total ingestions [2]	
			Moderate	Major
1992	11,803	10,769	57	1
1991	10,900	10,022	42	2
1990	10,910	9,883	55	4
1989	10,313	9,275	72	1
1988	10,475	9,483	104	1
1987	10,013	9,024	94	5
1986	11,676	10,622	71	15
Total	76,090	69,078	495	29

[1] Products included for the 1989–1992 data are pediatric multiple vitamin tablets with iron. Products included for the 1986–1988 data are pediatric multivitamin type products of unspecified dosage form.

[2] Only the 1992 data report moderate and major outcomes for children under 6 years of age. In 1992, 52 such moderate outcomes and 1 major outcome were reported.

Likewise, CPSC reports that, based upon data from its National Electronic Injury Surveillance System (NEISS) (NEISS is a probability sample of hospital emergency rooms in the United States that is used by the CPSC to measure the magnitude of the injury problem associated with consumer products and to provide a source for followup investigations of selected cases), there was a significant upward trend in the estimated number of hospital emergency room-treated iron ingestion cases involving children under 5 years of age in the 1980 to 1993 period. Every annual estimate in the 1980 to 1985 period was smaller than every annual estimate in the 1986 to 1993 period. The estimated average number of cases annually was 1,240 for the 1980 to 1985 period and 3,170 for the 1986 to 1993 period (Ref. 1).

2. CPSC Case Reports

CPSC considers iron-containing products to be potentially hazardous to

children and, thus, has taken a number of significant steps designed to reduce the risk from these products. As part of its efforts, CPSC has collected detailed information on pediatric iron poisoning fatalities and has also conducted followup (from NEISS data) investigations of incidents of nonfatal pediatric iron ingestion where the victim was taken to a hospital emergency room. In order to evaluate the available data on specific occurrences of iron poisoning as fully as possible, FDA obtained from CPSC the case reports on 37 fatal pediatric poisonings (Ref. 21) and on 70 NEISS followup investigations of nonfatal pediatric iron ingestions for the years 1986 to 1993 (Ref. 22). These data are described below and are summarized in Tables 4 and 5.

Table 4 summarizes the data obtained from CPSC on 37 iron poisoning fatalities of young children since 1986. Among these fatalities, the average age of the victim was 16.8 months. In 25 of these 37 deaths, the iron potency of the implicated product was reported. These 25 products contained, on average, 63 mg iron per dosage unit. The lowest reported potency of an iron-containing product involved in these pediatric deaths was 40 mg iron per dosage unit. The potency of the iron-containing product involved in the 12 other deaths was not reported.

Table 4 shows that, in 21 of the 37 fatalities, information on the number of tablets or capsules consumed by the victim was reported. Among these 21 reports, the average number of iron tablets or capsules consumed by the victim was 39.

Table 4 also shows that in 56 percent of these 37 pediatric deaths (21/37), the iron-containing product visually appeared to be packaged in child-resistant packaging (CRP), and more specifically, in containers with apparently child-resistant closures (CRC). In 16 percent of the deaths (6/37), the iron-containing supplement was not packaged in CRP. Among the remaining deaths (10/37), the type of packaging was not reported.

TABLE 4.—PEDIATRIC DEATHS FROM IRON EXPOSURE REPORTED TO CPSC FROM 1986–1993

Case Report	Year	Age[1]	Packaging	Number of tablets	Rx[2]	Potency
1	1986	15	CRC[3,4]	15	Yes	65 mg[5]
2	1986	14	No Lid	NR	Yes	70 mg
3	1986	24	NR[6]	NR	NR	NR
4	1987	11	CRC[7]	70	Yes	65 mg
5	1987	21	Non-CRC	5	NR	40 mg
6	1988	16	NR	NR	NR	60 mg
7	1988	17	Non-CRC	10–30	Yes	NR
8	1988	18	CRC[8,9]	NR	Yes	65 mg
9	1988	19	CRC[9]	≥14	Yes	65 mg
10	1988	18	CRC[9]	NR	Yes	NR
11	1989	18	CRC[4]	20	NO	65 mg
12	1989	9	CRC[10]	98	NR	65 mg
13	1990	10	Non-CRC	40	Yes	65 mg
14	1990	11	Non-CRC	18	Yes	65 mg
15	1990	12	CRC[10]	NR	Yes	NR
16	1990	15	CRC[9]	30–35	Yes	65 mg
17	1990	16	NR	NR	Yes	NR
18	1990	36	CRC[9]	30	Yes	NR
19	1991	9	CRC[4]	15–35	NR	65 mg
20	1991	13	CRC[7]	30–40	Yes	NR
21	1991	14	Non-CRC	60–80	Yes	65 mg
22	1991	15	CRC[10]	30	Yes	65 mg
23	1991	16	NR	NR	NR	NR
24	1991	18	NR	NR	NR	65 mg
25	1991	21	CRC[4]	90	No	65 mg
26	1991	24	NR	NR	NR	NR
27	1991	16	CRC[11]	NR	No	65 mg
28	1991	36	CRC[11]	20–40	Yes	65 mg
29	1992	11	NR	40	NR	65 mg
30	1992	12	CRC[4]	NR	NR	NR
31	1992	15	NR	50	Yes	60 mg
32	1992	16	CRC[9]	40	Yes	60 mg
33	1992	20	CRC[7]	NR	Yes	65 mg
34	1992	16	NR	NR	Yes	60 mg
35	1992	18	CRC[11]	35–40	Yes	NR
36	1992	17	CRC[10]	NR	Yes	65 mg
37	1993	14	Non-CRC	NR	Yes	NR
		Avg=	Total:	Avg=	Total:	Avg=63
		16.8	CRC=21	39	Yes=	Range=
		Range=	Other=	Range=	24	40–70
		9–36	16	5–98	No=3	NR=12
					NR=	
					10	

[1] Age in months

[2] Even though these products were obtained by prescription (Rx), some information suggests that they were not drug products, but rather, they were dietary supplements dispensed by pharmacists for third party reimbursement purposes.

[3] Child-resistant closure.

[4] No information in case report on who opened the CRC; or the CRC was not involved in the accidental poisoning. *Total=5.*

[5] All potency levels have been converted from weight of the iron salt to iron contents. Potency is expressed as mg iron per dosage unit.

[6] No Reported (NR) or stated as unknown in the case report.

[7] Opened by sibling or another child (either actually or possibly). *Total=3.*
[8] Container was dual use—conventional and child resistant.
[9] Opened by victim (actually or possibly). *Total=6.*
[10] Left opened by the mother, or not closed properly. *Total=4.*
[11] CRC defective. *Total=3.*

Among the 21 reported pediatric poisoning deaths that involved iron-containing products packaged in CRP, Table 4 shows that 29 percent (6/21) of these deaths resulted from iron-containing products whose child-resistant package was reportedly opened (actually or possibly) by the victim. In 14 percent (3/21) of these deaths, the CRP was reported to have been opened (actually or possibly) by another child. An adult was reported to have opened the CRP in 19 percent (4/21) of the pediatric iron poisoning deaths. Among the remaining reports of pediatric iron deaths in which the iron-containing product was packaged in child-resistant containers, the means of opening the container were not identified in 24 percent (5/21). The CRP was reported to be defective in 14 percent (3/21) of these deaths.

Table 5 shows the total amount of iron ingested in the fatal poisoning incidents in which both the amount of tablets ingested and the iron potency of these tablets were reported. Among 17 fatalities, in all but 1 case, the iron potency of the tablets was 60 to 65 mg, and with 1 exception (the same reported case), the calculated amount of iron ingested was at least 900 mg.

The 70 case reports of NEISS followup investigations of nonfatal pediatric iron ingestions involved 80 children. The 80 children were either treated in the emergency room and released or hospitalized for a period of time. Table 6 summarizes these case reports. The average age of the children was about 31 months.

TABLE 5.—TOTAL AMOUNT OF IRON INGESTED IN PEDIATRIC DEATHS [1]

Case report	Number of tablets	Potency, mg iron/ dosage unit	Total ingestion, mg
1	15	65	975
4	70	65	4,550
5	5	40	200
9	≥14	65	910
11	20	65	1,300
12	98	65	6,370
13	40	65	2,600
14	18	65	1,170
16	30–35	65	1,900–2,275
19	15–35	65	975–2,275
21	60–80	65	3,900–5,200
22	30	65	1,950
25	90	65	5,850
28	20–40	65	1,300–2,600
29	40	65	2,600
31	50	60	3,000
32	40	60	2,400

[1] Calculated on information reported in only 17 case studies. Range: 200–6,370 mg of iron.

TABLE 6.—NONFATAL PEDIATRIC EXPOSURES TO IRON—DATA REPORTED TO CPSC FROM 1986–1993

	Age [1]	Package	Ingested [2]	Rx [3]	Potency [4]	Type [5]	Open [6]	T&R [7]	Serum [8]	Symptoms
1	12	CRC [9]	1	NR	NR	Tablets	Mother	Yes	NR	NR
2	24	Non-CRC	1–2	No	NR	Tablets	—	Yes	NR	NR
3	48	No Lid	Unknown	NR	NR	Pills	—	Yes	NR	NR
4	20	CRC	Unknown	NR	NR	Tablets	Victim?	Yes	NR	NR
5	24	No Lid	10–15	No	NR	Pills	—	Yes	NR	NR
6	10	CRC	1	No	NR	Tablets	Victim	Yes	NR	NR
7	36	NR [10]	Unknown	NR	NR	Pills	NR	Yes	NR	Diarrhea
8	48	NR	Unknown	NR	NR	Pills	NR	Yes	NR	Diarrhea
9	11	CRC	15	No	NR	Pills	Victim	No	Yes	Vomiting
10	24	CRC	8	Yes	NR	Prenatal	Victim?	Yes	NR	NR
11	12	CRC	3	NR	64mg	Prenatal	Sibling	Yes	NR	NR
12	24	CRC	1–2	Yes	NR	Prenatal	Victim	Yes	NR	NR
13	16	CRC	Unknown	Yes	NR	Prenatal	Victim	Yes	No	None
14	17	CRC	6–8	Yes	NR	Prenatal	Victim	Yes	NR	NR
15	26	Non-CRC	Unknown	Yes	65mg	Prenatal	—	Yes	No	NR
16	15	CRC	2	Yes	NR	Prenatal	Victim	Yes	No	NR
17	16	CRC	5	Yes	60mg	Anemia	Victim	No	NR	Vomiting
18	16	CRC	3–15	Yes	NR	Prenatal	Victim	No	NR	Vomiting
19	36	Non-CRC	Unknown	Yes	NR	Pills	—	Yes	NR	NR
20	15	CRC	50	Yes	NR	Pills	Victim	No	NR	Vomiting
21	22	Non-CRC	0	Yes	60mg	Pills	—	Yes	NR	NR
22	29	CRC	Unknown	Yes	NR	Pills	Victim?	Yes	Yes	Vomiting
23	19	Not original	Unknown	NR	NR	Prenatal	—	Yes	NR	Vomiting, Lethargic
24	23	CRC	4	Yes	NR	Prenatal	Victim	Yes	NR	NR
25	20	CRC	30–50	NR	NR	Prenatal	Sibling	No	Yes	Vomiting, turned blue
26	59	Non-CRC	1	No	NR	Prenatal	—	Yes	NR	Vomiting
27	23	CRC	1	Yes	NR	Prenatal	Victim	Yes	NR	Vomiting
28	20	CRC	Unknown	Yes	65mg	Tablets	Victim?	Yes	NR	NR
29	21	NR	Unknown	NR	NR	Prenatal	NR	Yes	NR	NR
30	36	CRC	Unknown	Yes	NR	Prenatal	Victim	Yes	NR	NR
31	26	CRC	Unknown	Yes	NR	Prenatal	Victim	Yes	NR	Vomiting, drowsiness

TABLE 6.—NONFATAL PEDIATRIC EXPOSURES TO IRON—DATA REPORTED TO CPSC FROM 1986–1993—Continued

	Age[1]	Package	Ingested[2]	Rx[3]	Potency[4]	Type[5]	Open[6]	T&R[7]	Serum[8]	Symptoms
32	14	CRC	4–5	Yes	65mg	Prenatal	Victim	Yes	Yes	Lethargic
33	48	CRC	30	NR	18mg	Multivitamins.	Victim	Yes	NR	NR
34	24	CRC	32	NR	NR	Children's .	Victim	Yes	NR	NR
35	36	CRC	1	Yes	NR	Multivitamins.	Victim	Yes	Yes	NR
36	46	CRC	Unknown ..	No	NR	Children's .	Victim	Yes	NR	NR
37	24	CRC	Unknown ..	No	NR	Children's .	Sibling	Yes	NR	NR
38	59	CRC	20–25	No	NR	Children's .	Victim	Yes	NR	Lethargic
39	24	CRC	20–25	No	NR	Children's .	Sibling	Yes	NR	Lethargic
40	24	CRC	36	No	NR	Children's .	Sibling	Yes	Yes	NR
41	26	CRC	Unknown ..	No	NR	Children's .	Victim?	Yes	Yes	NR
42	36	CRC	25	No	NR	Children's .	Mother	Yes	Yes	Vomiting
43	36	CRC	15	No	NR	Children's .	Victim?	NO	NR	NR
44	29	CRC	20	No	NR	Children's .	Victim?	Yes	NR	NR
45	44	CRC[9]	42	No	NR	Children's .	Victim?	Yes	NR	Diarrhea
46	39	CRC	30	No	NR	Children's .	Victim?	Yes	NR	NR
47	42	CRC	25	No	NR	Children's .	Victim	Yes	NR	Cramps, Diarrhea, Vomiting
48	36	Not original	NR	NR	NR	Children's .	—	Yes	NR	NR
49	42	CRC	15	No	NR	Children's .	Victim	Yes	NR	NR
50	38	CRC	16–24	No	NR	Children's .	Victim?	Yes	NR	NR
51	36	Non-CRC ..	NR	No	NR	Children's .	—	Yes	NR	NR
52	35	CRC	50	No	15mg	Children's .	Victim?	Yes	NR	NR
53	36	CRC	UnkNown ..	No	NR	Children's .	Cousin	Yes	NR	NR
54	33	CRC	60–80	No	NR	Children's .	Victim	Yes	NR	NR
55	36	CRC	40	No	NR	Children's .	Victim	Yes	Yes	NR
56	36	CRC	25–35	No	NR	Children's .	Victim	Yes	NR	Diarrhea
57	24	CRC	25–35	No	NR	Children's .	Sibling	Yes	NR	Diarrhea
58	36	CRC	8–10	No	NR	Children's .	Victim	Yes	NR	NR
59	60	CRC	8–10	No	NR	Children's .	Victim	Yes	NR	NR
60	44	CRC	9	No	NR	Children's .	Victim	Yes	NR	NR
61	3	NR	1	No	NR	Children's .	—	Yes	NR	Fever, Constipation
62	36	CRC	5–10	No	15mg	Children's .	Victim?	Yes	NR	NR
63	24	CRC	10	No	NR	Children's .	Victim	Yes	NR	Nausea, Dizziness
64	48	CRC	UnkNown ..	No	NR	Children's .	Sibling	No	Yes	Vomiting
65	24	Non-CRC ..	20–30	No	NR	Children's .	—	No	Yes	None
66	48	CRC	5–6	No	60mg	Children's .	Sibling	Yes	NR	NR
67	30	CRC	5–6	No	60mg	Children's .	Victim	Yes	NR	NR
68	24	CRC	75	No	NR	Children's .	Victim	Yes	NR	NR
69	36	CRC	58	No	NR	Children's .	Victim	Yes	Yes	NR
70	12	Non-CRC ..	NR	No	NR	Multivitamins.	—	Yes	NR	Vomiting
71	24	CRC	40	No	NR	Children's .	Victim	No	Yes	Hyperactive
72	24	CRC	30–40	No	NR	Children's .	Victim	No	NR	Vomiting, Lethargy, Turning Colors
73	24	CRC	30–40	Yes	NR	Children's .	Victim?	No	NR	Profuse Sweating
74	42	CRC	25	No	15mg	Children's .	Victim	Yes	NR	NR
75	24	CRC	25	No	15mg	Children's .	Sibling	Yes	NR	NR
76	36	CRC	20	No	NR	Children's .	Sibling	Yes	NR	Vomiting
77	72	CRC	20	No	NR	Children's .	Victim	Yes	NR	Vomiting
78	48	CRC	9–10	No	NR	Children's .	Sibling	Yes	NR	Vomiting, Diarrhea
79	36	CRC	5	No	NR	Children's .	Sibling	Yes	NR	Diarrhea
80	36	CRC	2	No	NR	Children's .	Victim	Yes	NR	None

[1] In months. *Avg.=31 Range 3–72.*
[2] Number of pills or tablets ingested.
[3] Even though these products were obtained by prescription (Rx), some information suggests that they were not drug products, but rather, they were dietary supplements dispensed by pharmacists for third party reimbursement purposes.
[4] All potency levels have been converted from the weight of the iron salt to iron contents. Potency is expressed as milligram iron per dosage unit. *Avg.=43.3 Range 15–65.*
[5] Type of iron-containing product. *Tablets and Pills=14 Prenatal and Anemia=18 Multivitamins=3 Children's=45.*
[6] Who opened the CRC. *Victim? (CRC Not closed properly, possibly aiding victim)=13 Victim 36 Other (—)=13 Family Member 15 NR=3.*

[7] T&R=Treatment and Release. *Yes=69 Treatment and Release Only. No 11=Hospitalized.*
[8] Elevated levels of iron in blood serum. *Yes=14 No=3 NR=63.*
[9] CRC=Child resistance closure. *CRC=64, Non-CRC=16.*
[10] Not reported (NR).

The types of products ingested were described as iron tablets, iron pills, prenatal vitamins, vitamins for anemia, multivitamins, and children's vitamins. Children's vitamins were the most numerous and were involved in 56 percent (45/80) of the cases, followed by prenatal vitamins in 23 percent (18/80). Sixty percent (48/80) of the iron products were nonprescription items, and 25 percent (20/80) were prescription items. (The remainder were not described.)

The average number of tablets ingested by the children was about 20 tablets, and the greatest number was 80 tablets. One child was taken to the emergency room as a precaution, but it was discovered that the child had not actually swallowed any tablets. The iron potency of the product was documented only in 13 case reports and in those, it ranged from 15 to 65 mg.

Most of the iron products (80 percent, 64/80) were reportedly packaged in CRP, whereas 10 percent (8/80) of the products were reportedly not packaged in CRP. In the remainder of the cases, the iron products were in packages with lost lids, the product had been removed from the original container, or no details were reported. The victims opened the CRP in 45 percent (36/80) of the cases. In 16 percent (13/80) of the cases, the victim was able to open the CRP because the lid was not secured tightly, whether by intent or accidentally, by an adult. A family member such as a sibling, cousin, or mother opened the CRP in 18 percent (15/80) of the incidents, allowing the victim access to the iron product.

Elevated iron serum levels were reported in 18 percent (14/80) of the reports, and normal levels were reported in 3 of the cases. However, most of the cases (79 percent, 63/80) did not report test results for serum iron. Eighty-six percent (69/80) of the cases were treated and released from the hospital, while 14 percent (11/80) were admitted to the hospital.

Symptoms, or lack of symptoms, were reported for 34 of the 80 children. The symptoms included diarrhea, vomiting, and lethargy. Gastrointestinal symptoms were the most common, vomiting occurred 18 times, diarrhea occurred 8 times, and 2 children suffered both vomiting and diarrhea. Fever and constipation were reported only for the 3-month old victim. Cramps, nausea, drowsiness, dizziness, hyperactivity, and profuse sweating were other symptoms that were documented only once each. A combination of at least two symptoms were documented for eight children.

Two of the pediatric iron poisoning incidents, including one fatality, occurred after an adult removed several dosage units from their original container and stored them in nonchild-resistant containers, as follows: (1) "The aunt took the prenatal vitamin pills out of their original container and placed them in a tin can that was half full of pennies." (Ref. 22, case report No. 23.)

(2) "For reasons as yet unknown, she (the mother) took them from the original container believed to be equipped with a child-resistant closure, and put them in a container that was not equipped with a child-resistant closure, possibly a vitamin bottle." (Ref. 21, case report No. 21.)

D. Response to the Epidemic

1. Petitions Submitted to FDA

FDA has received three citizen petitions requesting that the agency take various actions concerning labeling, packaging, and formulation for iron-containing products. One of the petitions suggested that the agency undertake efforts to educate the public about the danger of pediatric iron poisoning. The petitions were submitted by the American Association of Poison Control Centers (the AAPCC petition) (Docket No. 91P-0186/CP1) (Ref. 12); the Attorneys General of 34 States, Commonwealths, and Territories (the AG petition) (Docket No. 93P-0306/CP1) (Ref. 13); and the Nonprescription Drug Manufacturers Association (the NDMA petition) (Docket No. 93P-0306/CP2) (Ref. 23). The principal issues in these petitions are summarized in Table 7 and discussed in this section.

TABLE 7.—SUMMARY OF KEY ELEMENTS OF PETITIONS

Element	AAPCC	AG	NDMA
Warning labels.	X ≥30 Fe	X ..... All products	X All products
Packaging. Requirements .		X ..... Individual Blister ..... Packaging for. ≥30 Fe ...	X Eliminate CRP Exemption[1]
Reformulation.	X	X	X No sweet Outer coating On products ≥30 Fe
Education	X	.....	X

[1] Included in petition to CPSC.

a. *The AAPCC petition.* The AAPCC petition was submitted on April 30, 1991, and was supplemented by an additional submission by AAPCC on February 28, 1992. It was based upon pediatric poisoning data collected by the AAPCC National Data Collection System from 1983 through 1991. The petition stated that iron products are the leading cause of poisoning deaths in children under age six. A letter was submitted to the agency in support of the AAPCC petition by the American Academy of Pediatrics on February 17, 1993. The AAPCC petition requested that the agency take the following actions concerning the labeling and formulation of iron-containing products:

(1) *Labeling.* The petition requested that FDA declare labels on drug products and food supplements containing 30 mg or more of iron per dosage unit as misleading if the label does not clearly state that accidental pediatric ingestion of these products can be lethal.

(2) *Formulation.* The petition requested that the agency urge the industry to voluntarily reformulate iron-containing products containing 30 mg or more of iron per dosage unit in less attractive dosage units, specifically avoiding resemblance to popular candies.

The AAPCC petition also requested that the agency initiate an educational effort to alert the public and health professionals to the dangers of accidental pediatric ingestion of iron-containing products. The AAPCC stated that efforts need to be directed especially to parents, babysitters, daycare providers, and other consumers; to pediatricians, urging these health professionals to target parents at the 6-month visit; to obstetricians, urging these health professionals to educate mothers at the final postpartum visit; to other health professionals who prescribe

iron-containing products; and to pharmacists who dispense them.

b. *The AG petition.* The AG petition, submitted on August 16, 1993, cited data on injuries and deaths attributable to accidental iron poisoning in children reported to the AAPCC National Data Collection System and reported to CPSC through 1992. It requested that the agency take the following actions concerning the labeling, formulation, and packaging of iron- containing products:

(1) *Labeling.* For iron-containing products containing 30 mg iron or more per tablet or capsule, the petition requested that the agency promulgate a regulation requiring that the label bear a conspicuous boxed warning that states:

Warning—Keep away from children. Contains iron which can be harmful or fatal if swallowed by a child.

The petition recommended that this warning be in bold face type and in a color that contrasts with the background and with other printed material on the label and labeling.

The petition also recommended that immediately following the above boxed warning, the following information appear:

Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death.

For iron-containing products containing less than 30 mg iron per tablet or capsule, the petition recommended that the agency promulgate a regulation requiring that the label contain a conspicuous boxed warning that states:

Warning—Keep away from children. Contains iron which can be harmful or fatal in large doses if swallowed by a child.

The petition recommended that this warning also be in boldface type and in a color that contrasts with the background and with other printed material on the label and labeling.

(2) *Packaging*—The petition recommended that FDA require that iron-containing products containing 30 mg or more of iron per tablet or capsule be packaged in child-resistant individual blister packs.

(3) *Formulation*—The petition recommended that FDA prohibit the manufacture and sale of adult formulations of iron-containing products that look like candy or contain a sweet outer coating.

c. Nonprescription Drug Manufacturers Association petition.

The Nonprescription Drug Manufacturers Association (NDMA), a trade association that represents U.S. manufacturers and distributors of nonprescription medicines and vitamin and mineral products, submitted a citizen petition to FDA on October 15, 1993, in response to the AG petition. The NDMA petition requested that FDA adopt into regulation the newly initiated voluntary NDMA program on the labeling, packaging, and formulation of iron-containing products. NDMA stated that it submitted a similar petition to CPSC requesting that CPSC adopt into regulation the elements of the voluntary industry program that are under the regulatory jurisdiction of CPSC. The petition also requested that FDA deny the other citizen petitions submitted on iron-containing products and pediatric poisoning insofar as they would contradict, add to, or subtract from the NDMA program.

The NDMA petition requested that FDA adopt the following labeling, formulation, and packaging provisions:

(1) *Labeling.* Iron-containing products must bear on the primary container (or box for blister packaging, glassine envelope, etc.), conspicuously, prominently, and clearly distinguished from other labeling by type, color, or contrast, the following warning statement:

Warning: Close tightly and keep out of reach of children. Contains iron, which can be harmful or fatal to children in large doses. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

The petition stated that in circumstances in which the packaging did not involve a reclosable CRP element (e.g., cap to a bottle), the term "close tightly" would not need to appear in the warning statement.

(2) *Packaging.* The NDMA specifically requested that FDA deny the request made by the AG petition to require that iron- containing products containing 30 mg or more of iron per tablet be packaged in child-resistant individual blister packs. In support of this request, NDMA pointed out that its voluntary program calls for the packaging of all iron-containing products with 30 mg or more iron per dose in complying CRP (i.e., there will be no CRP-exempt sizes for this type of product). (See discussion on CRP requirements of CPSC in section II.B. of this document.) NDMA noted that its voluntary program is being carried out in conjunction with a national consumer education campaign that it launched with CPSC on September 27, 1993, in conjunction with CPSC's Conference on Pediatric Iron Poisonings and Fatalities, which was held on September 28, 1993, in Washington, DC.

(3) *Formulation.* The NDMA stated that iron-containing products with greater than or equal to 30 mg iron per solid dosage form will not be formulated with sweet outer coatings.

2. The Consumer Product Safety Commission Conference

CPSC held this conference because of the increase in iron poisonings of children. The objective of the conference was to provide a forum for health care professionals and representatives of government and industry to identify solutions to this problem. The conference included invited speakers from CPSC, AAPCC, Georgetown University, FDA, NDMA, the National Nutritional Foods Association (NNFA), and the Office of the New York State Attorney General. This conference highlighted the seriousness of the pediatric iron poisoning problem and the steps that were being taken to address the problem.

Factors that may have contributed to the increased incidence of pediatric iron poisonings were discussed, including the requirement by many women for iron supplementation during pregnancy; the use of iron-containing products in homes where small children are present; the ability of older siblings of potential victims to open CRP; the misconception that vitamin and mineral products are inherently safe; improper use or failure to properly close child-resistant closures; and the formulation of some iron-containing products to appear like candy, potentially explaining why some children consumed large quantities of tablets (30 to 100 tablets).

CPSC described the regulations that it issued in 1978 under the Poison Prevention Packaging Act, which require CRP on most drugs and food supplements with more than 250 mg of iron per container (see section II.B. of this document). CPSC noted that its Office of Compliance and Enforcement recently discovered that several manufacturers of iron-containing products were not using CRP, and that some of these manufacturers had voluntarily agreed to recall these products.

At this conference, FDA explained that most iron-containing products are regulated as dietary supplements under the food provisions of the Federal Food, Drug, and Cosmetic Act (the act). FDA noted that, although there are currently no specific regulations for iron-containing supplements, the general food safety and food labeling provisions of the act require that all foods, including iron-containing supplements, be safe under their intended conditions

of use, and that their labeling be truthful and nonmisleading. FDA also noted that iron-containing products that are regulated as drugs under the drug provisions of the act must be approved before marketing as safe and effective for their intended conditions of use and are subject to labeling and good manufacturing practice requirements.

The industry's voluntary efforts in response to the iron poisoning problem were described by representatives of NDMA and NNFA. NDMA described its newly initiated voluntary program of packaging, labeling, and formulation changes which it had petitioned FDA to adopt into regulation. NDMA also described the newly launched joint consumer education campaign that it had developed in cooperation with CPSC to inform adults how to protect children from accidental iron poisoning. (See section IV.B. of this document.)

NNFA stated that its members were adopting a voluntary program similar to NDMA's, with the added provision that iron will be limited to a maximum of 30 mg per dosage unit and 30 mg per recommended dose.

In an open discussion of possible solutions, several ways to address the problem of pediatric iron poisoning were suggested. These suggestions included:

(1) Labeling iron-containing products with statements warning that accidental ingestion by children can be lethal.

(2) Packaging changes for iron-containing products with 30 mg or more iron per dosage unit, including packaging these products in child-resistant unit-dose (e.g., blister) packages and not offering such products in packaging that is not child- resistant (no exempt sizes).

(3) Reformulating iron-containing products that resemble candy and that have a sweet outer coating to discourage consumption of large amounts by small children.

(4) Requiring prescription status for iron products, reducing the number of units per package, and closer monitoring of the iron status of pregnant women to determine whether iron supplementation is really needed.

(5) Multi-ethnic educational efforts to increase public awareness of the dangers associated with iron and patient counseling by obstetricians, gynecologists, and pharmacists, because many poisonings involve iron-containing drug products.

Several participants at the conference commended the trade associations for their voluntary programs. However, some participants urged that child-resistant unit-dose blister packaging, an element not included in the voluntary industry programs, be implemented as a significant measure to reduce the incidence of iron poisonings. The participants in the conference called upon industry, government, and the healthcare community to undertake efforts, including cooperative efforts, to address this problem.

E. The Scope and Purpose of this Document

The purpose of this document is to: (1) Propose requirements designed to reduce the risk of pediatric poisonings from the accidental ingestion of iron-containing products, (2) solicit additional information concerning the issue, raised in the petitions, of reformulating iron-containing products to avoid the resemblance to candy and to avoid use of a sweet outer coating, and (3) describe the efforts that FDA intends to undertake to respond to the need for public education concerning iron poisonings, reinforcing the NDMA/CPSC education campaign.

As stated above, the agency believes that the new requirements that it is proposing, in conjunction with CPSC's existing requirements for CRP for iron-containing products (see section II.B. of this document), will significantly reduce the risk of accidental pediatric iron poisoning. FDA and CPSC have worked together closely in coordinating their respective efforts toward this goal, and the two agencies intend to continue to work in close cooperation.

II. Regulation of Iron-Containing Products

A. Regulation by FDA

1. Types of Iron-Containing Products Addressed in this Proposal

This proposal addresses iron-containing products available as dietary supplements and as prescription drug products.

FDA defined "dietary supplement" as a food, not in conventional food form, that supplies a component to supplement the diet by increasing the total dietary intake of that component (59 FR 425, January 4, 1994).

Section 201(f) of the act (21 U.S.C. 321(f)) defines "food" as: (1) Articles used for food or drink for man or other animals; (2) chewing gum, and (3) articles used for components of any such article. In *Nutrilab Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983), the court noted that taste, aroma, or nutritive value were the primary reasons why people consume food. The *Nutrilab* court said that in section 201(f)(1) of the act, the statutory definition of "food" includes the common sense definition of food: "When the statue defines 'food' as 'articles used for food, it means that the statutory definition of food' includes articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value." Other courts have followed suit. (See *United States* v. *Undetermined Quantities of Cal-Ban 3000*, 776 F. Supp. 249, 254–255 (E.D.N.C.1991); *American Health Products Co.* v. *Hayes*, 574 F. Supp. 1498, 1508–1509 (S.D.N.Y. 1983), aff'd 744 F.2d 912 (2d Cir. 1984).)

Types of iron-containing products that meet the definition of a dietary supplement and are regulated as foods include products intended for use primarily to supplement the dietary intake of iron (iron supplements) and multi-vitamin/mineral supplements that contain iron. Products intended for use as iron supplements generally contain 30 mg or more or iron per dosage unit, while multi-vitamin/mineral supplements generally contain 18 mg or less of iron per dosage unit.

Under section 201(g)(1) of the act, drugs are defined as:

> (A) Articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C).

Iron-containing products that are regulated as prescription drugs include iron preparations that also contain folic acid and that are prescribed to meet requirements during pregnancy. These products are regulated as drugs because of the amount of folic acid that they contain. These products generally contain 30 mg or more of iron per dosage unit.

Thus, how an iron-containing product is regulated turns on its intended use.

2. Legal Authority for FDA Regulation of Iron-Containing Products

a. *Safety of iron and iron salts added to dietary supplements.* The act is intended to ensure that all food, including dietary supplements, is safe. The act does so, in part, by stipulating that no substances may be added to food unless they are safe. FDA has defined "safe" as meaning there is a reasonable certainty that no harm will result from the use of an ingredient in food (§ 170.3(i)(21 CFR 170.3(i)). The determination as to whether there is a "reasonable certainty of no harm" can

be made in a number of ways. The two most common are the existence of general recognition among qualified experts that the substance will be safe for its intended use (GRAS) (see § 170.3) or a determination by FDA that the use of the substance is safe (see sections 201(s), 402(a)(2)(C), and 409 of the act (21 U.S.C. 342(a)(2)(C) and 348)).

Under section 201(s) of the act, for a substance to be GRAS, general recognition of its safety must exist among experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The experts' conclusion as to the safety of the substance for its intended use may be based on either: (1) Scientific procedures, that is, published scientific evidence that provides the quantity and quality of scientific evidence that would justify listing the use of the substance as a food additive; or (2) in the case of a substance used in food prior to January 1, 1958, evidence derived from common use of the substance in food.

Under section 409(c)(1)(A) of the act, the agency is authorized to prescribe the conditions of safe use of the substance, including, but not limited to: "* * * specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by [the Secretary of Health and Human Services] to assure the safety of such use."

Section 402(a)(1) of the act also provides authority to take action to ensure that food is not harmful. It states:

> A food shall be deemed to be adulterated—(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

Using its authority under these sections of the act, FDA has reviewed the safety of various iron salts that are used in food. FDA listed reduced iron, ferrous gluconate, ferrous lactate, ferrous sulfate, ferric phosphate, ferric pyrophosphate, and ferric sodium pyrophosphate as GRAS nutrients in a regulation published in the **Federal Register** of November 20, 1959 (24 FR 9368). Subsequently, FDA listed iron and these compounds as GRAS "nutrients and/or dietary supplements" in a regulation published in the **Federal Register** of January 31, 1961 (26 FR 938). In addition, the ferrous salt of fumaric acid (§ 172.350 (21 CFR 172.350)) (originally promulgated as 21 CFR 121.1130 (29 FR 559, January 23, 1964) and iron-choline citrate complex (§ 172.350 (21 CFR 172.370)) (originally promulgated as 21 CFR 121.247 (28 FR 4509, May 4, 1963)) have been listed by the agency as food additives for use in foods for special dietary use.

In a final rule published in the **Federal Register** of September 5, 1980 (45 FR 58837), the agency divided the "nutrients and/or dietary supplements" category into separate listings for ingredients whose intended use was as a dietary supplement (part 182 (21 CFR part 182), subpart F) and for ingredients whose intended use was as a nutrient supplement in foods in conventional food form (part 182, subpart I). For example, reduced iron is listed as GRAS in § 182.5375 for use as a dietary supplement ingredient and in § 182.8375 for use in food in conventional form as a nutrient. Similarly, ferric phosphate (§ 182.5301), ferric pyrophosphate (§ 182.5304), ferric sodium pyrophosphate (§ 182.5306), ferrous gluconate (§ 182.5308), ferrous lactate (§ 182.5311), and ferrous sulfate (§ 182.5315) are listed as GRAS for use as dietary supplement ingredients and are listed in § 182.8301, 182.8304, 182.8308, 182.8311, and 182.8315, respectively, as GRAS for use as nutrients in food in conventional food form.

In a regulation published on May 12, 1988 (53 FR 16862), the agency affirmed that elemental iron (21 CFR 184.1375), ferrous ascorbate (21 CFR 184.1307a), ferrous carbonate (21 CFR 184.1307b), ferrous citrate (21 CFR 184.1307c), ferrous fumarate (21 CFR 184.1307d), ferrous gluconate (21 CFR 184.1308), ferrous lactate (21 CFR 184.1311), ferrous sulfate (21 CFR 184.1315), ferric ammonium citrate (21 CFR 184.1296), ferric citrate (21 CFR 184.1298), ferric phosphate (21 CFR 184.1301), and ferric pyrophosphate (21 CFR 184.1304) are GRAS for use as nutrient supplements, as that use is defined in 21 CFR 170.3(o)(20), and removed their listing from part 182, subpart I. However, in the final rule, FDA did not affirm that these iron salts are GRAS for use in dietary supplements (i.e., in forms such as capsules, tablets, or liquids) because there were insufficient data on their consumption as dietary supplement ingredients. However, these ingredients continue to be listed as GRAS for use in dietary supplements under part 182, subpart F.

Even though FDA has affirmed as GRAS the use of numerous iron salts in foods, there are differences in the toxicity of these various salts.

b. *Safety and efficacy of iron-containing drugs.* The act also authorizes FDA to regulate the marketing of any products to help ensure that the products are safe and effective for their intended uses. "New drugs" may not be introduced into interstate commerce unless they are the subject of approved new drug applications (NDA's)(25 U.S.C. 355(a)). The act defines a "new drug" as: (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions (21 U.S.C. 321(b)). In order to be approved, an NDA must contain adequate data to demonstrate that the drug product is safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)). In addition, for NDA approval, the product must be manufactured using current good manufacturing practice and the product labeling must not be false or misleading (21 U.S.C. 355(d)).

Section 411 of the act (21 U.S.C. 350) provides that the Secretary of Health and Human Services may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful except in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children (individuals under the age of 12 years), or by pregnant or lactating women.

Most of the iron-containing products that FDA regulates are considered dietary supplements. The iron-containing products that FDA currently regulates as drug products are generally prescription products and are so designated, in most cases, because they

contain an amount of folic acid that exceeds the amount in which folic acid may be used as a food additive (see 21 CFR 172.345).

FDA currently has no packaging or labeling requirements specifically for iron-containing drug products. As prescription drug products, these iron-containing products must comply with the labeling requirements of section 503(b)(2) of the act (21 U.S.C. 353(b)(2)) and 21 CFR part 201, as well as other applicable provisions.

B. CPSC Regulations

CPSC, under authority of the Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C 1471–1475), regulates the packaging of household substances, including food, drugs, and cosmetics, as these terms are defined under the PPPA. Under this authority, CPSC has promulgated regulations establishing special packaging[1] standards for several household substances, including noninjectable animal and human iron-containing drugs (16 CFR 1700.14(a)(12)) and dietary supplements (16 CFR 1700.14(a)(13)) containing a total amount of iron in a single package[2] equivalent to 250 mg or more per container.

For nonprescription covered products, the PPPA permits one type of package for each product to be sold without special packaging if all other package types of the product comply with the requirements. However, exempt packages must bear a conspicuous label stating: "This package for households without young children." CPSC may, by regulation, prescribe a substitute statement to the same effect for packaging too small to accommodate this statement.

In the case of prescription drugs, the PPPA allows for an exemption to such packaging requirements only when directed in the prescription or when requested by the purchaser.

CPSC provides for testing for special packaging in 16 CFR 1700.20. This regulation establishes test protocols to evaluate child-resistant effectiveness and adult accessibility to such packaging. Recently, CPSC proposed to amend 16 CFR 1700.20 to establish new test protocols under which CRP is evaluated (55 FR 40856, October 5, 1990, and 59 FR 13264, March 21, 1994).

In establishing these regulations, CPSC considered the degree and nature of the hazard to children from accidental acute overdose of dietary supplements and drugs containing iron. It found that special packaging is required to protect children from serious injury from ingesting iron-containing drugs and dietary supplements. This finding was based on: (1) Data from FDA's National Clearing House for Poison Control Centers (no longer in operation) and NEISS, which showed that products containing iron are frequently ingested by children under the age of 5 years; (2) published human experience data, symptomatology associated with many of the National Clearinghouse for Poison Control Centers ingestion reports, and data from death certificates, which showed that the accidental ingestion of 250 mg or more of iron has caused death or serious illness; and (3) the fact that iron-containing drugs and dietary supplements are normally stored in their original containers, and that many accidental ingestions of these products result from children gaining access to the contents of the original container (43 FR 17335, April 21, 1978).

III. Proposed Regulation

A. Labeling

1. Review of Labeling Issues in Citizen Petitions

As noted in section I.D.1. of this document, the AG and NDMA petitions agreed that iron-containing products should bear label warning statements. However, these petitions did not agree on what the warning should state, or on how it should appear on the label.

In requesting the labeling provisions described in section I.D.1. of this document, the AG petition stated that the hazard presented by iron-containing products is the result, in part, of the perception that they are nontoxic household products. Thus, according to this petition, they are likely to be left within easy reach of children and not kept properly secured. The petition also noted that these products are extremely attractive to children because of their typical candy-like appearance and sweet outer coating and pointed to case reports that illustrate how children ingest iron tablets in large quantities (see Table 4).

The AG petition stated that the recent increase in iron poisoning deaths among children might reflect an increase in the extension of primary health care, especially prenatal care. It noted: "While more doctors are prescribing prenatal iron supplementation to more women, there has been no concomitant increase in warnings regarding their potentially lethal effects."

The AG petition also noted that, while more women were using iron-containing products, the labeling of these products does not reflect the dangers inherent in their misuse:

> While labeling for a few multi-vitamins containing iron bears the statement that iron can be harmful in large doses, most iron supplements bear only the non-specific phrase, "Keep out of reach of children." Few, if any, packages of iron supplements contain the word "WARNING" or "CAUTION," words universally accepted as denoting danger, to alert the user to the dangers of iron overdose. Further, the meager statements that do exist are, for the most part, printed in the same color and type size as other material on the label and therefore fail to catch anyone's attention. The statements are often obscured within other small print on the labeling and are neither prominent nor specific enough to reach parents with a warning about these pills' potential fatal effect on children. Consumers who have no knowledge of iron's hazards before purchasing iron supplements will not gain that knowledge by purchasing the product and examining the label.

The AG petition presented data showing that many iron-containing products commonly available do not carry any label information conveying the need to keep the product out of the reach of children or conveying any message specific to iron poisoning. A summary, which was included as part of the AG petition, of the label information found on 25 commonly available iron-containing products revealed that 10 of the 25 did not include information on the label that the product should be kept away from children, and that 17 did not contain information stating that iron could be harmful. Six of the products had no cautionary information at all, and none of the products that did have cautionary information used the terms "WARNING" or "CAUTION," to accompany the statements on the label.

NDMA, in its petition, stated that its proposed warning label was more appropriate than that proposed in the AG petition because its warning goes beyond awareness in its focus and extends its message to include information that is preventive in nature, i.e., "Close tightly," and treatment oriented, i.e., "In case of accidental overdose seek professional assistance immediately."

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[1] "*Special packaging* means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time." 16 CFR 1700.1(b)(4).

[2] "*Package* means the immediate container or wrapping in which any household substance is contained for consumption, use or storage by individuals in or about the household and, for purposes of section 4(a)(2) of the act, also means any outer container or wrapping used in the retail display of any such substance to consumers * * *." 16 CFR 1700.1(b)(3).

NDMA also argued for allowing for flexibility in the manner in which the warning statement is to be applied to the label. The petition stated:

> It has been the experience of NDMA members in implementing the Association's Label Readability Guidelines that such factors as contrast, color, type size, substrate, paragraphing, etc. are inter-related in a complex way on labeling, such that goal-oriented flexibility is perhaps the most important principle in assuring prominence to special label language. That is to say, specifying a box, when boxed labeling may already be stipulated under NLEA regulations, is not necessarily as good a way to ensure prominence to label language as is a more flexible approach whose goal is to ensure that the language is conspicuous, prominent and clearly distinguishable from other labeling.

2. Agency Response

FDA considered the following questions in evaluating and responding to the labeling issues raised in the citizen petitions: (1) Should label warning statements that alert users to the potential dangers that iron-containing products pose to young children be required on these products? (2) If so, what legal authority does the agency have to require such statements on food and drug products? (3) What should the warning be required to state? and (4) How should the warning appear on the label?

a. *Should label warning statements be required for iron-containing products?* Based on the data in the AAPCC and AG petitions and in the CPSC case reports, iron-containing products can cause injury, including serious injury, and death when children gain access to these products. FDA finds from these data that the potential for harm exists for all three types of iron-containing products available, i.e., multi-vitamin/mineral supplements that contain iron, iron supplements, and iron-containing drugs.

Supporting this finding are the data cited in Tables 1, 2, and 3 that show that, since 1983, at least 40 deaths have been attributed to the accidental ingestion of iron supplements and iron-containing drugs, and that, since 1986, nearly 190 poisonings that were life threatening or that resulted in permanent injury, and over 2,000 poisonings requiring some form of treatment, have resulted from accidental ingestion of adult iron-containing products.

Further support is provided by the data in the CPSC case reports, which show 80 ingestions of iron leading to hospital emergency room visits with varying types of injury, including vomiting, lethargy, diarrhea, and elevated serum iron (see Table 6).

The data in Tables 4 and 6 show that in several documented poisoning incidents, children have ingested 30, 40, 50, or more tablets of iron-containing products when these amounts of tablets were accessible. Aside from the potential for such ingestion of iron-containing supplements and drugs to be fatal, the consequences of ingesting even multi-vitamin/mineral type products in these amounts is evident from Table 8. This table shows that an amount of iron that may produce symptoms of iron poisoning (i.e., 25 mg/kg) can be ingested by a 10 kg child if the child consumes 25 tablets containing 10 mg of iron each or approximately 14 tablets containing 18 mg each. (Ten mg and 18 mg of iron are the amounts typically contained in multi-vitamin/mineral supplements with iron including children's vitamins.) Based upon the data in Tables 4 and 6, ingestion of this many tablets is not atypical. Thus, FDA finds that injury can result anytime a small child is able to gain access to even the lowest potency iron-containing products available.

Further, the fact that over 2,000 reported poisoning incidents of varying severity have been recorded in recent years (Tables 2 and 3), and the fact that AAPCC reports that accidental iron poisoning is presently the leading cause of pediatric poisoning deaths, lead FDA to find that pediatric iron poisonings have occurred, and continue to occur, with significant frequency. Further, FDA finds that the fact that these poisonings continue to occur, even though there have been over 40 deaths from accidental iron ingestion (See Table 1), strongly suggests that many adults are not aware of the potential for serious harm or death in young children from accidental ingestion of iron-containing products. Support for this finding is provided by statements made by the parents of the victims in several of the poisoning incidents, described in the case reports obtained from CPSC as follows:

(1) "The mother stated that she thought the pills (prenatal iron pills) were just vitamins and would not harm the victim" (Ref. 21, case report No. 10).

TABLE 8.—NUMBER OF IRON-CONTAINING TABLETS INGESTED RESULTING IN TOXIC AND LETHAL DOSAGES

Potency of Iron Product, mg Iron per Dosage Unit	Number of Tablets Containing Toxic Dose (25mg/kg) for a 10 kg Child	Number of Tablets Containing Potentially Lethal Dose (100-250mg/kg) for a 10 kg Child[1]
10	25	100–250
18	14	55.5–139
30	8	33–83
60	4	16.5–41.5
100	2.5	10–25
130	2	7.5–19.5

[1] Values for a lethal dose cited by authorities generally range from 100 to 250 mg of iron per kg of body weight. The Attorneys General petition states that fatality has occurred at doses as low as 60 mg/kg.

(2) "She (the mother) said that she did not think he (the victim) had taken very many pills at the time, and that she was unaware of the danger of iron overdose" (Ref. 21, case report No. 20).

(3) "The mother stated that she called her sister and asked if iron tablets could hurt the victim. The mother stated, that her sister told her that the tablets were just vitamins and would not hurt the victim" (Ref. 21, case report No. 37).

(4) "The mother thought at the most if her son had taken more than a couple of the vitamins he would simply throw up and that would be the end of it. She had no idea what a dangerous situation her child was in" (Ref. 22, case report No. 62).

(5) "Later in the day (after child had ingested 30–40 iron tablets) the mother went to the pharmacy to get a prescription for the daughter's ear infection and she asked the pharmacist about the possible ingestion of iron tablets" (Ref. 22, case report No. 73).

In addition, as stated above, the data presented by the AG petition show that

few, if any, of the commonly available iron-containing products have carried label statements using terms such as "WARNING" or "CAUTION." Because these terms are universally accepted as connoting danger, they could be expected to promote awareness among adults of the danger that these products pose to young children and of the importance of preventing children from gaining access to these products.

Therefore, because the data demonstrate that: (1) Iron-containing products of all types can cause injury or death when small children gain access to them, (2) more than 2,000 poisonings have occurred over approximately 7 years and continue to occur, (3) a small child is at risk of injury any time he or she gains unlimited access to any iron-containing product, and (4) many adults are not aware of the potential for serious harm posed by iron-containing products, FDA tentatively concludes that it should require label warning statements for iron-containing products to ensure that adults are fully informed as to the potential of these products to cause devastating outcomes and, thus, to promote the safe handling and storage of these products.

b. *FDA's legal authority to require label warning statements on foods.* FDA's authority to require label warning statements on food products derives from sections 201(n), 403(a)(1), and 701(a) of the act (21 U.S.C. 321(n), 343(a)(1), and 371(a)). Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act states, "If an article (e.g., a food product) is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual." These statutory provisions, combined with section 701(a) of the act, which grants the agency authority to promulgate regulations for the efficient enforcement of the act, clearly authorize FDA to promulgate a regulation designed to ensure that persons using iron-containing multi-vitamin/mineral products and iron supplements will receive information that is material with respect to consequences that may result from the use of the product under its labeled conditions or under conditions that are customary or usual.

FDA requires label warning statements on certain types of protein products represented for use in reducing weight. The agency adopted this requirement in response to a series of sudden deaths of individuals, mostly young women, who consumed high protein, very low calorie diets (§ 101.70(d)(21 CFR 101.17(d)). Use of such diets was intended to achieve rapid weight loss. As a result of these deaths, which occurred in the late 1970's, FDA promulgated the warning requirement for such products to ensure that users of these products are aware of the potential adverse consequences of very low calorie protein diets, to indicate the necessity for appropriate medical supervision for persons on such diets, and to identify individuals, i.e., infants, children, or pregnant or nursing women, who should not use these products (49 FR 13679, April 6, 1984).

FDA's legal authority under sections 201(n), 403(a)(1), and 701(a) of the act to require a warning statement on dry, whole protein products was upheld in *Council for Responsible Nutrition* v. *Goyan*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,057 (D.D.C. 1980). In that case, the plaintiff asserted that the fatal consequences arising from the use of dry, whole protein products while dieting were not the result of the customary or usual use of these products, but rather, the result of unusual misuse of such products. Based on FDA's showing that the consumption of dry protein products could occur in the course of a diet, and that, under certain circumstances in dieting, serious adverse effects could arise from such use of these products, the court found that FDA properly invoked sections 201(n), 403(a)(1), and 701(a) of the act to impose a requirement that manufacturers warn consumers of the consequences that could result from the use of such products.

The facts presented by the evidence on iron poisonings parallel those that led the agency to require a warning on protein products. The use of iron-containing products in households where children are present is in no way an unusual practice. Multi-vitamin/mineral supplements with iron are routinely taken by children, and products of this type specifically intended for use by children are widely available and commonly sold. Iron supplements and adult vitamin/mineral supplements with iron are frequently taken by pregnant women (often with a prescription) and other women of child-bearing age because they require more iron than other adults (see discussion in section I.A. of this document). Yet, the evidence on poisonings and deaths shows that the use of any type of iron-containing product in such households can readily lead to accidental injury or death if children gain access to the products, even though the products are not intended to be used by children or to be taken in the numbers in which iron-containing tablets or capsules are consumed when poisonings occur. Thus, *Council for Responsible Nutrition* v. *Goyan* provides strong support for the agency's authority to require label warning statements concerning the risk of accidental poisoning from iron-containing food products.

Based upon FDA's authority under sections 201(n), 403(a)(1), and 701(a) of the act, the agency proposes to require that manufacturers of iron-containing dietary supplements (i.e., children's and adult's multi-vitamin/mineral supplements that contain iron and products intended for use as iron supplements) disclose information about their products in the form of a label warning statement that would appear on such products in the manner described below.

c. *FDA's legal authority to require label warning statements for drugs.* The act authorizes FDA to regulate the marketing of drug products to ensure that such products are properly labeled. To carry out the public health protection purposes of the act, FDA, among other things, monitors drug labeling to ensure that it provides accurate information about drug products.

Under section 502(a) of the act (21 U.S.C. 352), a drug product is misbranded if its labeling is false or misleading in any particular. The provisions of section 201(n) of the act concerning failure of the labeling to reveal material facts are applicable to drugs as well as to foods in determining whether labeling is misleading. In addition, under sections 505(d) and (e) of the act (21 U.S.C. 355(d) and (e)), FDA must refuse to approve a new drug application, and may withdraw approval for a product, if the product's labeling is false or misleading in any particular.

These statutory provisions, together with section 701(a) of the act, clearly authorize FDA to promulgate a regulation designed to ensure that patients using drugs will receive information that is material with respect to consequences that may result from the use of a product. (See

Pharmaceutical Manufacturers Association v. *Food and Drug Administration*, 484 F. Supp. 1179 (D. Del. 1980), aff'd per curiam, 634 F.2d 106 (3d Cir. 1980).)

The act also authorizes FDA to regulate the marketing of drug products to ensure that such products are safe and effective for their intended uses. Iron-containing drug products are not safe for their intended use as currently labeled, in part because the labeling fails to warn of iron-containing products' toxic effects in children. Adults are, therefore, not aware of the need to prevent children from ingesting these products. Because the labeling fails to warn adequately that these products may produce toxic effects in children, iron-containing products are not being used as intended; that is, even though they are not intended for children, they are handled in a way that permits their ingestion by children.

The act anticipates that new information about the safety or effectiveness of marketed drugs may require changes in labeling to reflect necessary limitations on use or to warn of previously unanticipated hazards (see e.g., 21 U.S.C. 355(e)). FDA has required by regulation that manufacturers provide warning statements for specific drug products (e.g., drugs for internal use which contain mineral oil, 21 CFR 201.302; isoproterenol inhalation preparations, 21 CFR 201.305; acetophenetidin (phenacetin)-containing preparations, 21 CFR 201.309). The impetus for requiring warnings for each of these products or product classes was evidence of risk in a specific patient population or from a specific use of the product. FDA responded to these risks by requiring warnings to help patients use prescription drug products more safely and effectively. For example, given the particular risk of severe paradoxical bronchoconstriction associated with repeated, excessive use of isoproterenol inhalation preparations, FDA requires that warning information to patients be included as part of the label and as part of the instructions included in the package dispensed to patients (See 21 CFR 201.305). The specified warning statement may be placed on the immediate container with a statement to the pharmacist not to remove it or may be included in a package with instructions to pharmacists to place the warning on the container prior to dispensing (see 21 CFR 201.305(c)(2)).

Based upon FDA's authority under sections 201(n), 502(a), 505 and 701(a) of the act, the agency is proposing to require that manufacturers of prescription iron-containing products disclose information about the risks presented by their products in the form of a warning statement that would appear on such products in the manner described below.

d. *What should the label warning be required to state?* FDA has considered what information should be required in the warning statement to ensure that, as required by sections 201(n), 403(a)(1), 502(a), and 505 of the act, users of iron-containing products are made aware of the potential consequences of their use, i.e., that the labeling of iron-containing products states the facts that are material with respect to the consequences that may result from the use of these products. The proposed warning statements in the AG and NDMA petitions contained the various information elements as shown in Table 9. FDA tentatively concludes that to fulfill the requirements of the act, the warning statement should incorporate some elements from both of these petitions, as well as other elements that are designed to ensure that the statement performs its function. In reaching this tentative conclusion, FDA considered several factors.

FDA agrees with the AG petition that the term "Warning" is necessary to alert the user to the potential consequences of the use of the product, that is, to the dangers of iron overdose. This term is universally accepted as denoting danger. FDA tentatively concludes that the potential for iron-containing products to cause death or serious injury any time a small child gains access to the product warrants the use of this term.

FDA tentatively concludes that the statement must bear the instruction to "Keep away from children." Because a child is at risk of serious injury or death any time he or she gains access to iron-containing products, this statement is a material fact about the consequences of use of the product and is also necessary to ensure the safe use of the product.

TABLE 9.—ELEMENTS OF PETITIONERS' WARNING LABELS

Information Elements	Petitioner		
Fe[1] Overdose Warning Label Elements	AAPCC	AG	NDMA
"WARNING" (stated first)	.....	X	X
"Close tightly" (for bottles)	.....	.....	X
Accessible to children	.....	X[2]	X[3]
Consequences of Fe overdose (injury and death)	X (For products. ≥ 30 mg Fe; no suggested language)	X	X
Warning language dose dependent	.....	X[4]	.....
Reference to "large doses" as presenting a greater hazard	.....	X[5]	X[6]
Listing of symptoms	.....	X[7]	.....
Treatment action	.....	.....	X[8]

[1] Fe denotes iron.
[2] "Keep away from children."
[3] "Keep out of reach of children."
[4] Products ≥ 30 mg Fe: "Contains iron which can be harmful or fatal if swallowed by a child."
[5] Product < 30 mg Fe: "Contains iron which can be harmful or fatal in large doses if swallowed by a child."
[6] All iron-containing products: "Contains iron, which can be harmful or fatal to children in large doses."
[7] Products ≥ 30 mg Fe: "Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death."
[8] "In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately."

FDA also recognizes that the warning needs to be crafted to reflect the type of packaging used. Iron-containing products may be packaged in unit-dose packages, e.g., blister packs, or in containers with closures, e.g., a bottle

with a cap. FDA tentatively concludes that for iron-containing products packaged in unit-dose packages, the warning statement should include the instruction "Keep in original package until each use." This statement instructs the user not to misuse the product by removing more dosage units from their individual packs than will be ingested at one time. This instruction is important because such misuse can result in poisoning if children gain access to the dosage units that have been removed from their original packaging. This instruction was not specifically requested by any of the petitions. Because some incidents of pediatric iron poisoning have occurred after adults removed multiple dosage units from their original containers and stored them in nonchild-resistant vessels (see section I.C. of this document), however, the agency tentatively concludes that this statement is necessary to ensure that the product is properly used.

The agency concurs with the NDMA petition that the statement "Close Tightly" should be included in the warning statement for containers with closures. Such a statement provides information on how to maintain the child-resistance of the container. FDA finds that this message is a material fact. FDA bases this finding, in part, on the fact that some incidents of iron poisoning have occurred even though the product was in child-resistant packaging. Children were able to gain access to iron products because the child-resistant closure was not properly secured (See section I.C. of this document). Thus, to ensure that iron-containing products are used safely, the child-resistance of the packaging must be maintained, and FDA tentatively concludes that inclusion of the statement "Close Tightly" is necessary to ensure that condition of use is maintained.

FDA also tentatively concludes that the label must include the information "Contains iron, which can harm or cause death to a child." This statement informs the user or the serious and potentially life-threatening nature of the consequences that can occur when a child ingests an uncontrolled amount of these products.

FDA also tentatively concludes that the label must state: "If a child accidentally swallows this product, call a doctor or a poison control center immediately." FDA agrees with the NDMA petition that treatment-oriented information should be included on the label because it informs attending persons in a poisoning incident of the need to take immediate action that could save the child's life and about what that action should be. Thus, it relates directly to the consequences of use of the product.

FDA does not believe that the warning statement should be based upon or contain information relating to the potency of the iron product (i.e., different statements for products above and below 30 mg per dosage unit as requested by the AG petition, or reference to "large doses" of iron as a factor in determining whether poisoning may occur). The agency tentatively finds that such statements could cause members of the public to attempt to determine whether a large dose has been taken in a possible poisoning incident. Because most people are not capable of determining what dosage of iron may be nontoxic, toxic, or capable of causing serious harm or death, qualified medical or poison control personnel should determine the significance of the dose a child has ingested.

Nor does there appear to be any reason to require that the statement include reference to the specific types of consequences that may arise from acute overdosage, i.e., nausea, vomiting, cardiovascular collapse, as requested by the AG petition. FDA does not believe that this information would materially add to the label statement that overdose can cause harm or death, and fears that it may lead to the erroneous conclusion that, because a child does not exhibit one of the listed symptoms, the child is not in danger.

e. *How should the warning appear on the label?* FDA agrees with the AGs' contention that the warning statement should appear prominently on the label of iron-containing products to effectively convey its message. Further, the act specifically requires, in sections 403(f) and 502(c), that information required to appear on the label of a food or a drug be prominently placed and appear with such conspicuousness, as compared with other printed matter, as to render it likely to be read by the ordinary individual under customary conditions of use.

However, the AG petition provided no evidence to support the specific presentation elements that it requested for the warning statement, i.e., that it be boxed, in boldface type, and in a color that contrasts with the background and with other printed material on the label or labeling. The agency is not aware of any basis on which it can conclude that any of these specific elements are necessary to ensure that the statement appears on the label in a prominent and conspicuous manner.

Further, in the agency's rulemaking that mandated warning statements on certain protein products, the agency decided not to mandate specific requirements for letter size and other format elements. However, the agency did require that the warning statement appear "prominently and conspicuously on the principal display panel of the package label" (21 CFR 101.17). FDA made a determination to give manufacturers flexibility to design their own label warning formats, while ensuring that the statement is prominent and conspicuous, so that consumers are given adequate notice of the information contained in the warning (47 FR 25379 at 25382, June 11, 1982). In addressing the placement of the label warning, the agency noted that the seriousness and nature of the risk associated with the use of protein products in very low calorie diets was sufficient to require placement of the warning statement on the principal display panel (49 FR 13679 at 13689).

Section 201(k) of the act defines the term "label" as "a display of written, printed, or graphic matter upon the immediate container of any article" and further states that a requirement "that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper if any there be, of the retail package of such article * * *." Thus, if FDA requires a label warning statement to appear on the immediate container of iron-containing products, it would also have to appear on the retail package of such a product if that package is not the immediate container.

As stated above, the fact that iron-containing products have resulted in reports of 2,000 poisonings in children over approximately 7 years provides evidence that many adults are not aware of the potential for serious harm posed by iron-containing products. Based on this fact, FDA tentatively finds that there are sufficient grounds to require that the label warning statement be printed directly on the immediate container of the product, i.e., the container that holds the tablet or capsule, and on the principal display panel of the retail package, i.e., an outer box, if such package is not the immediate container (many iron-containing products are packaged in this manner). If a product is sold in unit-dose packaging, this requirement will mean that the product will have to bear the warning directly on each unit-dose package or on a strip of unit-dose packages in such a way that separating the unit dose packages would not destroy the warning labeling.

The placement of the warning statement on the principal display panel of the retail package will make it likely that the warning statement will be seen at the time the product is purchased. The statement will inform the purchaser of the product's potential to cause poisoning and of the need to keep the product away from children when it is brought into the house. FDA tentatively concludes that placement of the warning statement on the principal display panel is necessary to fulfill the requirement of sections 403(f) and 502(c) of the act, that information required to appear on the label of a food or a drug be placed with conspicuousness (as compared with other printed matter) as to render it likely to be read by the ordinary individual under customary conditions of use. Moreover, placement of the warning statement on the principal display panel is consistent with the requirement that FDA established for protein product warning statements discussed previously. In both cases, the products in question could cause serious, even life-threatening, problems if misused. Thus, FDA tentatively concludes that the standard of conspicuousness established in the protein products case should also be adopted for iron-containing products.

The agency tentatively concludes that placement of the warning statement on the immediate container is also necessary to fulfill the requirement of sections 403(f) and 502(c) of the act because, under customary conditions of use, the retail container is frequently disposed of, and individuals other than the purchaser may use the product. Therefore, the warning statement must be printed on the immediate container if this statement is to perform its function throughout the life of the product.

Regulating the placement of the warning is consistent with other labeling requirements that the agency has imposed. In 21 CFR 201.314(h)(1) and (h)(2), FDA has required that the labeling of orally or rectally administered aspirin and aspirin-containing drug products intended for sale without prescription bear a warning that reads: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin." The warning must appear on the immediate container labeling. In cases where the immediate container is not the retail package, the retail package must also bear the warning statement. (see 51 FR 8180, March 7, 1986).

FDA tentatively concludes that the objectives of the proposed regulation regarding the packaging and labeling of iron-containing products will be best met if the agency requires that the proposed warnings appear on the immediate container. In case the strip packaging or individual unit-dose packages are removed from the box in which they are sold to the consumer, or in case a strip of unit-dose packages is transferred by a pharmacist to a vial, each unit-dose package, or strip of unit dose packages, would bear the warning that FDA considers essential to the safe use of these products. The warning would remind adults not to remove the iron-containing products from the unit-dose package. In addition, it would ensure that each time an adult takes one of these products, he or she is reminded of the danger that the product poses to children.

In addition, if the warning accompanies each tablet or group of tablets, an adult who finds a child eating the product will know to call for help immediately and will know, when asked by a health care professional, that the ingested tablets contain iron.

FDA is not proposing specific requirements for the graphics (e.g., type size, bold type) of the warning statement but is proposing to require that the label warning appear prominently and conspicuously on the immediate container of the product and on the principal display panel of the retail package, so that consumers are given adequate notice of the information contained in the warning. These proposed requirements for the warning statement are consistent with the requirement FDA established for protein products. FDA tentatively concludes that they will effectively achieve, through placement rather than graphical requirements, the objective sought by the AG petition of reaching consumers who have no knowledge of iron's hazards.

If FDA adopts the regulations that it is proposing, manufacturers will have the flexibility, as requested in the NDMA petition, to design their own label and warning notice formats. The agency is requesting comments on the most efficient way to ensure that warnings on the immediate container will accompany every tablet until the time it is used. Suggestions about the placement and design of unit-dose packaging that can best accommodate the required warnings are invited.

FDA also specifically solicits comments on whether the general requirement that the label warning appear prominently and conspicuously on the label is adequate. Should the agency more explicitly define in its regulation the level of prominence and conspicuousness that it expects? If so, what should the agency require? The agency notes, for example, that in a final rule that required a new warning on Reye syndrome for aspirin, it specifically stated that the requirement of "prominence" in its regulations meant that manufacturers of aspirin and aspirin-containing drug products had to use an attention-getting statement, such as "see new warning" on the label for at least 1 year (53 FR 21633, 21635, June 9, 1988). Similarly, in the final rule on nutrition labeling that FDA adopted in response to the Nutrition Labeling and Education Act of 1990, FDA specified a number of format elements to ensure that the nutrition facts label would be readily observable and comprehensible (see 58 FR 2079, January 6, 1993). FDA requests comments on whether, to ensure that the warning statement will have its intended effect, the agency should specify more completely how the warning should be presented on iron-containing products.

3. Proposed Labeling Requirements

Having tentatively concluded that label warning statements should be required on iron-containing products, and having evaluated the information that the warning statement should include, FDA is proposing to amend its regulations by adding new § 101.17(e) for foods, and new § 310.55 for drugs, to require label warning statements for iron-containing products offered in solid oral dosage form. As noted above, under these proposed regulations, the warning statement that must be used will depend upon how the product is packaged. For products that are packaged in unit-dose packaging (e.g., blister packs) the agency is proposing to require the following warning:

> WARNING—Keep away from children. Keep in original package until each use. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

Under this proposal, this warning statement will be required for all iron-containing products packaged in unit-dose packaging. Therefore, it would be required to appear: (1) On the labeling of products containing 30 mg or more iron per dosage unit, which are subject to the proposed requirement for unit-dose packaging described below (see section III.B. of this document); and (2) on the labeling of products that contain less than 30 mg iron per dosage unit but

that are packaged voluntarily in unit-dose packaging.

For products that contain less than 30 mg iron per dosage unit and that are packaged in any form of packaging other than unit-dose packaging, e.g., containers with child-resistant closures, the agency is proposing to require the following warning:

WARNING—Close tightly and keep away from children. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

The agency may conduct focus group research to evaluate consumer understanding of the proposed warning messages and to ensure that the messages are not misleading. Focus group research involves gathering small, representative groups of consumers (no more than nine consumers per group) and leading then in a directed discussion of the research topic. For the present research, consumers will provide feedback as to their level of understanding of the warnings and the degree to which the specific wording of the messages is believable, relevant, confusing, or irritating. The agency intends to consider the results of the focus group research in arriving at any warning statement that is included in the final regulations. FDA will make a report on the results of its research available for public comment before it issues the final regulations.

B. Packaging

1. Review of Packaging Issues in Citizen Petitions

Two of the citizen petitions suggested that FDA take action with respect to the packaging of iron-containing drugs and dietary supplements. Both petitions recommended packaging requirements as a means of reducing pediatric poisonings from ingestion of multiple doses of drugs and dietary supplements containing 30 mg or more iron per dosage unit.

The AG citizen petition requested that FDA use its authority under the act to require that all iron-containing drugs and dietary supplements containing 30 mg or more iron per dosage unit be packaged in child-resistant blister packs.

The NDMA petition recommended that FDA incorporate into its regulations the NDMA-initiated voluntary program to address pediatric poisonings by such iron-containing products. This voluntary program includes, in part, a proviso that all iron-containing products currently subject to CPSC's special packaging regulations that contain 30 mg or more of iron per dosage unit be packaged in CRP's, and that there be no exemption to CPSC's child-resistant special packaging requirements for these types of products. As discussed previously, NDMA's voluntary program also specifies labeling statements and includes an educational program. Implicit in NDMA's recommendation is the view that CRC's, labeling warning statements, and consumer education programs are sufficient to ensure the safe use of iron-containing products.

2. Agency Response

FDA considered the following questions in evaluating and responding to the packaging issues raised in the citizen petitions: (1) Can educational efforts and label warning statements alone sufficiently reduce pediatric iron poisonings? (2) Are noncomplying child-resistant packages a principal cause of iron poisoning deaths? (3) Are additional packaging requirements necessary to ensure the safe use of certain iron-containing products? (4) What is FDA's legal authority to regulate packaging for foods and drugs? (5) Should child-resistant blister packaging be required for iron-containing products?

a. *Can educational efforts and label warning statements significantly reduce pediatric iron poisonings?* FDA agrees with NDMA that educating consumers on the proper use of CRC's and on the hazards posed by iron-containing drugs and supplements is very important. However, based on the available evidence, even if all CRC's were properly used, these closures could not have prevented the majority of the 37 reported fatalities. Improper use of CRC's was reported in only 4 of the 21 (19 percent) pediatric iron fatalities known to involve child-resistant packaging (Table 2). Educational programs and label warning statements should help to increase proper use of reclosable CRC's, and thereby help to prevent some pediatric iron-poisonings. However, FDA knows of no information showing that a consumer education program, either that recommended by NDMA or any other such program, will be adequate to ensure that children will not be able to defeat even properly closed CRC's, or that improper use of such closures will cease. In the absence of such information, FDA believes that measures beyond consumer education programs are necessary to ensure that the use of certain iron-containing products is safe.

FDA also tentatively finds that label warning statements will not be sufficient to ensure the safe use of these products. This tentative conclusion is based on the fact that label warning statements do not in any way bar access to the product. Label statements are an important educational tool for making adults aware of the significant consequences for young children if they gain access to the product. Young children, however, cannot read and have little judgment. Thus, a warning statement is likely to have little or no effect on their efforts to gain access.

The available data show that poisonings are occurring in large measure because of the efforts of children. Table 4 shows that in 9 of the 21 reported pediatric poisoning deaths that involved iron-containing products packaged in containers with CRC's, the victims gained access to multiple doses of iron-containing product by their own efforts or through the efforts of another child. Most of these children were under 51 months of age. Thus, a label warning statement is unlikely to have any meaning or significance to them.

FDA requests comments on its tentative conclusion that label warning statements are not sufficient to ensure that the use of certain iron-containing products will be safe. Comments that bear on the effectiveness of labeling warning statements to deter young children from directly gaining access to these products will be most compelling if they contain supporting data and information.

As stated above, FDA believes that label warning statements will help to reduce the incidence of pediatric poisoning because they will ensure that adults are aware of the pediatric toxicity of iron and will encourage responsible adults to properly reclose and store iron-containing products. However, FDA is concerned that warning statements alone will not prevent the misuse of CRP's that has contributed to the epidemic of iron poisonings of children. FDA notes that CRP's themselves are a de facto warning that the contents of the package present hazards for children. Yet, in 21 of the 26 pediatric poisoning deaths in which the type of packaging was reported, the product was packaged in containers with CRC's (Table 4).

Furthermore, the effectiveness of label warning statements is generally considered to be dependent on several factors including, but not necessarily limited to: The personal relevance of the warning information; familiarity with the warning information; perceived hazard from the product; and desensitization or habituation to warnings after repeated exposures (Ref. 24). Moreover, a report on the effectiveness of a labeling and educational program to prevent pediatric poisonings from accidental

ingestion of prescription drugs shows that labeling and educational programs are not always sufficient to prevent pediatric poisonings, and that, in some instances, additional packaging safeguards are necessary to ensure the safe use of certain substances (Ref. 25). Therefore, FDA tentatively concludes that label warning statements will not be sufficient to ensure the safe use of certain iron-containing products.

FDA finds that iron-containing drugs and dietary supplements pose a unique hazard to young children. The pediatric hazard presented by these products is directly related to their iron content. As discussed above in section I.B. of this document, ingestion of 25 mg or more iron per kg of body weight is considered a toxic dose, and ingestion of 100 to 200 mg iron per kg of body weight can be lethal. Once a potentially lethal dose of iron has been ingested and absorbed, medical intervention to halt the toxic progression of iron poisoning is difficult and often unsuccessful. Successful treatment for iron poisoning is determined primarily by the amount of iron ingested and how rapidly medical intervention occurs. In light of the risk of pediatric iron poisonings with irreversible and potentially fatal consequences that is presented by higher potency iron-containing products, and of the inherent limitations on the effectiveness of labeling and educational programs, FDA tentatively concludes that it would be inappropriate to rely solely on these measures to ensure the safe use of these products.

b. *Are noncomplying CRP's a principal cause of iron poisoning deaths?* The NDMA contends that new packaging requirements beyond those outlined in its petition are not necessary to reduce the incidence of pediatric iron poisonings. The NDMA petition asserts that the available data on pediatric iron-poisonings are deficient to the extent that it cannot be determined whether products associated with the poisonings were packaged in compliance with CPSC's packaging requirements, and it suggests that iron-containing products packaged in noncompliant CRP's are the principle cause of pediatric iron-poisonings. However, NDMA provided no information to support its view.

FDA has carefully examined the available information on pediatric iron poisonings and could find no evidence to support the NDMA's contention that the iron-containing products associated with these poisonings were packaged in CRP's that did not comply with regulations established by CPSC. In the absence of such evidence, FDA can find no basis on which to conclude that noncompliant, child-resistant special packaging is the primary cause of pediatric iron-poisonings.

c. *Are additional packaging requirements appropriate?* FDA tentatively concludes that full compliance with CPSC's CRP requirements, even if there are warning statements in labeling of iron-containing products and appropriate educational programs, will not be adequate to ensure the safe use of certain iron-containing drugs and dietary supplements if bottle and closure packaging were to continue as the predominant means of packaging such products. FDA recognizes that each of these measures either has been successful in limiting the number of poisonings or can be reasonably expected to be effective in reducing the number of poisonings. However, given the potentially fatal outcome that can result from pediatric iron-poisoning, FDA is not persuaded that these measures are adequate to ensure the safety of the use of certain iron-containing drugs and dietary supplements. FDA tentatively concludes that to reduce the incidence of pediatric iron poisonings to a level that would permit the agency to conclude that there is a reasonable certainty of no harm from the use of these products, it is necessary to require a specific type of physical barrier to access these products. Therefore, FDA tentatively concludes that additional packaging requirements are necessary.

FDA requests comments on this tentative conclusion. The agency is particularly interested in receiving comments that bear on the effectiveness of different types of packaging to limit pediatric access to toxic amounts of iron. Comments will be most persuasive if they are supported by studies and other data and information.

d. *Consideration of legal authority of FDA and other agencies to require specific packaging measures for foods and drugs.* In its consideration of what action to take concerning the packaging of iron-containing drugs and dietary supplements to ensure their safe use, FDA recognized that it must act within the limits of its statutory authority and consider the statutory authority of other government agencies. As noted above, under the PPPA, CPSC has authority to regulate the packaging of household substances. Under the PPPA, CPSC can establish special packaging performance standards. Thus, by regulation, CPSC has established special packaging standards and performance criteria for special packaging, 16 CFR 1700.15 and 1700.20, respectively. However, the PPPA specifically limits CPSC from establishing regulations that require specific packaging designs, product content, and package quantity for household substances, including food and drugs.

i. *Packaging for iron-containing dietary supplements.* The act provides FDA with broad authority to ensure that food is safe and wholesome. In particular, the act prohibits the adulteration of food in sections 301 and 402 (21 U.S.C. 331 and 342) and requires, in sections 409(a) (21 U.S.C. 348(a)) and 402(a)(2)(C), that all food additives be listed for use by FDA before they are added to food.

In section 409(a), the act deems a food additive to be unsafe unless its use conforms to the conditions specified in the listing regulation. These conditions include, but are not limited to, specifications as to the particular food or classes of food to which the additive may be added, as to the manner in which the additive may be added to such food, and any directions or other labeling or packaging requirements for such additive deemed necessary to ensure the safety of such use (section 409(c)(1)(A) of the act. Thus, under the act, the agency is authorized to specify packaging requirements for a food additive when it finds that use of such packaging is necessary to ensure the safe use of the additive.

In section 201(s), the act provides an exemption to the food additive definition for substances that are generally recognized as safe (GRAS) under the conditions of their intended use. FDA has issued regulations delineating conditions under which use of certain substances is GRAS. If the conditions of a particular use of a substance are not those that are generally recognized as safe, the use is not GRAS, but subject to regulation under the food additives provisions of the act.

Should FDA determine that a particular type of packaging is necessary to ensure the safe use of iron substances in dietary supplements, either as GRAS substances or as listed food additives, then any use of iron substances in dietary supplements that does not involve use of that type of packaging would constitute a use of an unapproved food additive and render the dietary supplements adulterated under the act.

ii. *Packaging for iron-containing drug products.* Section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)) states that a drug shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with,

current good manufacturing practice to assure that such drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

A drug product may be safe and effective as manufactured but used in an unsafe and ineffective manner. Current good manufacturing practice is, to some extent, an evolving standard. To remain "current," a manufacturer must take into account advances in technology as well as new information about the use of the product including, but not limited to, information about any dangers associated with use of the drug product. Manufacturers must use this knowledge to alter, adapt, or change their manufacturing procedures to ensure that all possible measures have been implemented to eliminate known dangers. Therefore, advances in technology and new information about dangers associated with a drug product can mean that further steps by the manufacturer are necessary to guard against such foreseeable dangers, in order to hold the drug product in a manner that ensures its safety and, thus, comports with current good manufacturing practice.

FDA has promulgated regulations to ensure that, among other things, drug products are held, pending use by the intended consumer, in a manner that ensures their safety (Parts 210 and 211 (21 CFR parts 210 and 211)). The term "held" includes not only manufacturing and shipping time, but also the time from point of purchase to consumer use. Thus, manufacturers are responsible for the manner in which their products are held pending actual consumer use, and they are responsible if the packaging that they use is not adequate to prevent unintended ingestion of iron by children.

The regulations are replete with examples of FDA's authority to regulate the manufacturer beyond the point of shipping the product from the manufacturing site. For example, § 211.94(b) requires that container closure systems "provide adequate protection against *foreseeable external factors* in storage and *use* that can cause deterioration or contamination of the drug product (emphasis added)." This regulation requires that manufacturers protect against deterioration or contamination occurring during storage of drug products throughout the chain of distribution, up to the point of use by the consumer.

Under section 501(a)(2)(B) of the act, manufacturers also are responsible for preventing intentional misuse of a drug product. In 1982, in response to a series of capsule tamperings, FDA promulgated a regulation (§ 211.132) that requires tamper-resistant packaging for all over-the-counter (OTC) human drug products except dermatologics, dentifrices, and insulin (47 FR 50442). The agency's action assured greater package integrity and product security beyond the point of manufacture. FDA's authority to require tamper-resistant packaging is found primarily in section 501(a)(2)(B) of the act.

Significantly, the health risk that prompted the tamper-resistant packaging regulation was not attributable directly to manufacturing or packing practices that contravened the current good manufacturing practice regulations in effect at that time. Rather, despite compliance with existing regulations, drug product quality was compromised because of previously unforeseeable and unintended intervention by persons other than the consumer.

Because tamper resistant packaging was a means to obviate a newly apparent danger, and because tamper-resistant packaging technology was available, current good manufacturing practice mandated that it be used.

Similarly, in 1989, recognizing the persistent vulnerability of the hard-capsule dosage form, FDA amended the tamper-resistant regulation to require that OTC products marketed in two-piece, hard-gelatin capsules be packaged using at least two tamper-resistant features (54 FR 5227, February 2, 1989). Likewise, in 1994, the agency proposed to amend the tamper-resistant regulation to require that the packages for all OTC human drug products marketed in two-piece, hard-gelatin capsules be sealed (59 FR 2542, January 18, 1994). The proposed amendment is part of "the agency's continuing review of the potential public health threat posed by product tampering," and was proposed to "address specific vulnerabilities in the OTC market and to improve consumer protection." (59 FR 2543). In the preamble to the proposed rule, FDA recognized that, although the packaging used at the time of the latest poisoning incidents met FDA requirements in effect at that time, the packaging was not designed to reveal visible evidence of tampering. The proposed rule would change "tamper-resistant" to "tamper-evident" to underscore the fact that current packaging technology is not invulnerable to tampering and would require packaging that not only erects barriers to tampering, but also alerts the consumer to signs of tampering.

In addition, in September 1993, FDA published a regulation that requires the imprinting of solid oral dosage form drug products for human use (See 58 FR 47948, September 13, 1993). The regulation requires that every such product be imprinted with a code that allows identification of the drug product and its manufacturer or distributor. The regulation will ensure, among other things, that consumers and health care professionals will have this information available in the event of an emergency. The imprinting rule, like the proposed rule for iron-containing products, responds to concerns that are related to consumer use of drug products rather than concerns focused on the integrity and composition of such products.

The proposed rule, therefore, like those pertaining to tamper-evident packaging and drug imprinting, is intended to enhance the safety of drug products, specifically iron-containing drug products. The recent statistical data available to FDA demonstrate that the current manner of holding iron-containing drug products until their use by the intended consumer fails to ensure that the drug products will be safe because large numbers of children are ingesting such products and suffering serious injuries or death. Existing technology permits additional safeguards, such as child-resistant blister packs, to be used for holding iron-containing drug products. Given the known dangers and the ability to minimize or eliminate such dangers through the use of existing technology, FDA tentatively concludes that current good manufacturing practice dictates that unit-dose packaging be used.

e. *Should child-resistant blister packaging be required?* Requiring child-resistant blister packaging of iron-containing drugs and supplements, as recommended by the AG petition, is one packaging approach to reduce the incidence of pediatric iron-poisoning fatalities. This approach can be viewed as embodying three distinct packaging components: (1) Require unit-dose packaging; (2) require a specific type of unit-dose packaging (i.e., blister packs); and (3) require CRP's.

FDA recognizes that unit-dose packaging provides certain packaging features that reclosable containers do not provide. Products packaged in unit-dose packaging require that the packaging be opened for each individual dosage unit. The additional time and effort needed to open each unit restricts the number of doses available for ingestion during the time that a child has access to the package. In contrast, a multi-dose reclosable package (i.e., a bottle and closure) allows a child access to all of its contents once the closure is opened. In addition, the effectiveness of

child-resistant unit-dose packaging does not depend upon adults' properly resecuring a cap as is the case with reclosable CRP's. Therefore, FDA tentatively concludes that unit-dose packaging of products will contribute in a significant, over and above the protections provided by warning statements and CRP's, to reduce children's access to potentially fatal doses of product.

This tentative conclusion is supported by studies of the pediatric accessibility of products in different types of conventional (i.e., nonchild resistant) packaging. The results from these studies show that unit-dose packaging, in comparison to snap type and screw cap closure packaging, will limit access to multiple doses of product by young children. Studies of pediatric accessibility of product packaged in conventional unit-dose "pouches," conventional unit-dose "blister cards," and containers with conventional "snap type" and "screw cap" closures have been reported. Children, 42 to 51 months old, participated in each of these studies. Results from the study of conventional pouch packaging show that 55.5 percent of the children (n = 200) were unable to access more than eight tablets in 10 min (Ref. 26). In a similar study of conventional blister card packaging 64 percent of the children (n = 200) were unable to access more than eight tablets in 10 min (Ref. 27). In contrast, studies of pediatric accessibility of conventional "snap type" and "continuous threaded type" packaging show that most young children are able to gain access to products packaged in these types of conventional packaging in a relatively short period of time. Results from studies of "snap type" packaging show that with upward opening forces of less than 3 lb (average 1.9 lb), 96 percent of the children (n = 650) were able to open such packaging within 12 to 75 seconds (Ref. 28). Results from studies of pediatric accessibility of conventional, 33 mm diameter, "screw type" packaging and having caps with 2, 4, 6, and 8, torque-inch-pounds (TIP) rotational closing forces, show that approximately 100 percent of the children (n = 400) were able to open the packaging within an average of 11 seconds. Fifty-four percent of the children were able to open "screw type" packaging with rotational closing forces of 10 to 25 TIP within 71 seconds (Ref. 29).

As noted above, blister packaging is one type of unit-dose packaging. However, FDA does not agree with the AG petition's contention that blister packaging is necessary to ensure the safe use of iron-containing drugs and supplements. FDA tentatively finds that requiring a specific type of unit-dose packaging may be more restrictive than necessary if other types of unit-dose packaging accomplish the same objective. As discussed above, other types of conventional unit-dose packaging provide a comparable length of time for children to open as that required by conventional blister packaging.

With regard to the child-resistant component of the AG petition's recommendation, FDA notes that CPSC has established regulations that require CRP's for iron-containing drugs and dietary supplements in packages that contain 250 mg or more total iron (16 CFR 1700.14(a)(12) and (13)). In addition, CPSC has promulgated regulations for performance standards to establish the effectiveness of CRP's (16 CFR 1700.20). FDA finds that establishing CRP's standards for iron-containing drugs and dietary supplements therefore would be redundant and could place an unnecessary regulatory burden on manufacturers of such iron-containing products. Furthermore, requiring CRP's for all iron-containing products with 30 mg or more iron per dosage unit would circumvent the intention of the PPPA to allow access by elderly and handicapped persons who are unable to use such household substances when packaged in compliance with CRP's requirements. Therefore, FDA is not proposing to separately require CRP's of iron-containing drugs and dietary supplements.

3. Proposed Packaging Requirements

FDA is proposing to amend its regulations to establish safe conditions of use for iron-containing products by requiring that all such products that contain 30 mg or more iron per dosage unit be packaged in nonreusable, unit-dose packaging. FDA tentatively concludes that the use of iron and iron salts in products at potencies at or above 30 mg iron per dosage unit is not safe (and, therefore, is not GRAS) unless the food to which it is added, or the drug which contains it, is packaged in a manner that is adequate to prevent unintended ingestion by children. Thus, while iron and several of its salts will continue to be listed as GRAS under 21 CFR part 182 for use as dietary supplements and under part 184 (21 CFR part 184) for use as nutrient supplements, FDA is proposing to add § 170.55, which will require unit-dose packaging when iron or iron salts are used at a level of 30 mg or more per dosage unit in dietary supplements. Section 170.55 will also apply to approved food additive uses of iron salts in foods for special dietary and nutritional uses. Unit-dose packaging of drug products that contain 30 mg or more of iron per dosage unit is required under proposed § 310.518(a).

a. *Rationale for requiring unit-dose packaging for iron-containing products with 30 mg or more iron per dosage unit.* FDA is proposing to require unit-dose packaging for iron-containing drugs and supplements with 30 mg or more iron per dosage unit to ensure that the use of these products is safe. FDA's tentative conclusion to use 30 mg per unit-dose as the threshold for requiring unit-dose packaging is based on its consideration of a number factors including: (1) The amount of ingested iron that can cause pediatric fatality; (2) the amount of ingested iron that can cause significant iron poisoning; (3) the average number of dosage units associated with pediatric fatalities; (4) the types and potency of iron-containing products associated with pediatric iron poisoning fatalities; (5) information on how iron products are sold; and (6) the citizen petitions that were submitted to FDA. These factors pointed to the use of 30 mg per unit-dose as a threshold.

As discussed above, the toxicity of any iron ingestion is related to the total amount of iron ingested and absorbed (section I.B. of this document). Ingestion of 250 mg iron per kg of body weight (2.5 g total iron for a 10 kg child) is typically considered to be a lethal dose of iron. However, there have been reports of fatalities from ingestion of lesser amounts (less than 2.5 g) of iron, and the available data bear this out. For example, Table 5 shows that several pediatric fatalities have been associated with ingestion of approximately 1 g of iron. Moreover, the amount of iron that can cause serious adverse effects is given as 60 mg/kg (section I.B. of this document). For a 10 kg child this translates to 600 mg of iron.

FDA recognizes that there is variability among individuals with respect to the lethal dose of iron. Because of this variability, and because of the variable size and age of children at risk, FDA tentatively concludes that, to protect the wide range of susceptible children, it is necessary through packaging measures (unit-dose packaging) to limit pediatric access to iron-containing drugs and dietary supplements at potencies that can be reasonably expected to provide 1 g of iron. Restricting pediatric access to this amount of iron by packaging measures will substantially reduce the potential for a fatal or significant iron poisoning outcome should an accidental pediatric

ingestion of iron-containing products occur. As discussed above, because of the time and effort needed to access products contained in unit-door packaging, the likelihood that young children will be able to ingest a lethal amount of iron will be significantly reduced, thereby reducing the likelihood that they will be seriously injured or die.

In the 37 case reports of iron poisoning fatalities available, the average number of dosage units ingested by the pediatric victim was 39 tablets or capsules, with a range of 5 to 98 (Table 2). FDA notes that ingestion of 39 tablets or capsules at potencies of 25 to 30 mg iron per dosage unit is sufficient to provide a potentially lethal dose of iron (i.e., approximately 1,000 mg) to a young child.

As for the types of products that have been involved in pediatric iron poisonings, none of the 37 pediatric fatalities was reported to be associated with a multivitamin/mineral supplement product. All of the products reported to be involved in these fatalities were either single or double nutrient products that were provided for use as prenatal supplements. Single or double nutrient iron-containing products generally contain 30 mg or more iron per dosage unit.

As for the potency of the products involved, all of the pediatric fatalities were reported to be associated with iron-containing products at potencies of 40 mg iron or more per dosage unit. FDA is not aware of any pediatric iron poisoning fatalities associated with iron-containing products whose potency was less than 40 mg iron per dosage unit. Moreover, only 1 of the 37 pediatric fatalities was reported to be associated with an iron-containing product that contained less than 60 mg iron per dosage unit. Thus, FDA observed that requiring unit-dose packaging of products that contain 30 mg or more iron per dosage unit will provide about a two-fold margin of safety from the potency of products that have usually been associated with pediatric fatalities.

The information available to the agency shows that products that contain 30 mg or more iron per dosage unit are primarily sold to women of childbearing age for prenatal use. Prenatal iron-containing products may be obtained as dietary supplements or prescription drug products. FDA notes that all of the iron-containing products associated with the 37 pediatric poisoning fatalities were apparently obtained as prenatal drugs or supplements. FDA finds that prenatal iron-containing drugs and supplements present the greatest potential for pediatric iron poisonings and fatalities because of their iron content, and because they are likely to be available in households with young children. Prenatal iron-containing products are likely to be in households with young children either because they remain in the household after childbirth, or because young children are present in the household during pregnancy.

Fourth, FDA notes that both the AG and NDMA citizen petitions recommended 30 mg iron per dosage unit as an appropriate level to establish additional safeguards to reduce the incidence of pediatric iron poisonings.

Therefore, FDA is proposing unit-dose packaging for all dietary supplements and drugs containing 30 mg or more iron per dosage unit. FDA tentatively concludes that unit-dose packaging will reduce the incidence of pediatric poisonings by providing the additional safeguards necessary to limit pediatric access to a potentially fatal amount of iron.

b. Practical effect. As discussed above, CPSC's child-resistant packaging regulations require that any iron-containing drug or dietary supplement packaged in a container with 250 mg or more iron must be packaged in accordance with their child-resistant packaging regulations (16 CFR 1700.14(a)(12) and (a)(13)). Therefore, FDA anticipates that manufacturers and distributors of drugs and dietary supplements containing 30 mg or more iron per dosage unit, and containing 250 mg or more total iron per package, under this proposed action and CPSC's current regulations (16 CFR 1700.14(a)(12) and (a)(13)), a manufacturer or packer will have the option of packaging the product in child-resistant unit-dose packaging (e.g., child-resistant blisters, child-resistant pouches), or of exercising its right to an exemption to CPSC's special packaging requirements to allow access by elderly or handicapped persons. However, under this proposed rule, in the latter case, the products will have to be packaged in conventional unit-dose packaging and will be subject to CPSC's requirements for exempt packaged products (16 CFR 1700.5).

FDA tentatively concludes that, regardless of which packaging option a manufacturer or packer uses, unit-dose packaging of all iron-containing drugs and supplements that contain 30 mg or more per dosage unit will ensure the safe use of such products by limiting unintended access to such products by young children.

In proposing this action, it is not FDA's intention to circumvent the aim of the PPPA to allow access by elderly and handicapped persons who may be unable to use such household substances when packaged in CRP's. The agency requests comments on the effect that this proposed packaging requirement will have on the accessibility of iron-containing drugs and dietary supplements to elderly and handicapped persons.

c. *Iron-containing drug products that are removed from and dispensed in other than unit-dose packaging are adulterated and misbranded.* In order to be exempt from the requirement in section 502(f)(1) of the act that a drug bear adequate directions for use, a prescription drug product for human use must bear, among other things, a statement, directed to the pharmacist, specifying the type of container to be used in dispensing the drug product to maintain the product's identity, strength, quality, and purity (21 CFR 201.100(b)(7)). However, directions for repackaging are "not required for prescription drug products packaged in unit-dose, unit-of-use, or other packaging format in which the manufacturer's original package is designed and intended to be dispensed to patients without repackaging." (Id.) If FDA ultimately determines that unit-dose packaging is necessary to ensure the identity, strength, quality, and purity of iron- containing drug products, the agency would consider such products that are dispensed to consumers in other than unit-dose packaging to be adulterated and misbranded. Products marketed by the manufacturer in unit-dose packaging would remain exempt from the requirement for repackaging instructions because FDA expects that pharmacists will not compromise such packaging systems.

FDA has, in certain cases in the past, prohibited pharmacists from repackaging products because the original manufacturer's packaging was necessary to ensure the product's identity, strength, quality, and purity. In 1972, FDA concluded that improper packaging of nitroglycerin preparations was causing substantial loss of potency of the drug. Commonly used plastic containers and strip packaging failed to prevent appreciable evaporation of nitroglycerin from nitroglycerin tablets. FDA determined that it was necessary to require that these products be packaged and dispensed in glass containers to ensure the potency of the product ((37 FR 15859, August 5, 1972); 21 CFR 250.300 (1973)). In addition, manufacturers were required to include a statement directed to pharmacists that the product should be dispensed only in

the original, unopened container (21 CFR 250.300(b)(1973)).

FDA revoked the nitroglycerin packaging and labeling requirements in 1985 because action taken by FDA and the United States Pharmacopeial Convention, Inc., after publication of the requirements, had made them unnecessary and duplicative (50 FR 7584, February 25, 1985). When it proposed to revoke the regulation, FDA observed that the U.S.P. monograph for sublingual nitroglycerin tablets duplicated most of the packaging and labeling requirements that initially had been set forth in the rule (49 FR 24031, June 11, 1984). In addition, FDA found that the suitability of any packaging not in conformance with the rule or the monograph under CGMP regulations would have to be shown to FDA by adequate data (id.).

Like the nitroglycerin regulation, this proposed regulation regarding iron-containing products is intended to address a public health problem that, FDA has tentatively concluded, can be alleviated by requiring specific packaging. As was the case with nitroglycerin before FDA required specific packaging, iron- containing products are not safe as currently packaged. FDA has tentatively determined that it is necessary to prohibit repackaging by pharmacists in order to protect product integrity and to provide the greatest assurance that iron-containing products will be used safely and as intended.

FDA recognizes that pregnant women can receive their iron supplements by way of third-party reimbursement, which generally requires that a health care professional prescribe the supplements. These women present their prescriptions to pharmacists who, often, repackage iron dietary supplements in pharmacy vials.

FDA recognizes the vital importance of iron supplements to prenatal health care and emphasizes that the proposed rule should not diminish the availability of iron tablets to pregnant women or to any other patient population. FDA expects that pharmacists will dispense the tablets in their original unit-dose packaging. Under the proposed rule, pharmacists would be free to dispense iron-containing products in the manufacturer's box, or in any other outer container, as long as the original unit-dose packaging remained intact.

FDA does not believe that the proposed mandatory packaging and labeling regulation will encroach upon the practice of pharmacy. Under the proposed requirement, products will reach the pharmacy in unit-dose packaging with a warning statement printed directly on the immediate wrapping or container. FDA tentatively concludes that such a requirement, rather than representing an encroachment on the practice of pharmacy, is necessary to ensure that consumers receive adequate warning about the serious dangers associated with the use of iron-containing drugs.

IV. Other Issues

A. Formulation and Appearance of Iron-Containing Products

The AG petition recommended that FDA prohibit the manufacture and sale of adult formulations of iron-containing products that look like candy or contain a sweet outer coating. The AAPCC petition asked FDA to urge the industry to voluntarily reformulate iron-containing products containing 30 mg or more of iron per dosage unit to be in less attractive dosage units, specifically avoiding resemblance to popular candies.

NDMA asked FDA to reject the recommendation from the AG petition for several reasons. First, NDMA stated that "candy can be—and is—made to look like just about any other consumable product. Once a supplement manufacturer decides on a shape, size, color—of which there are limited selections—for a supplement product, a candy manufacturer could choose independently to introduce a candy that looks like that dietary supplement." Second, NDMA stated that it is not known what a pill looks like to a very young child. "A very young child puts everything into his or her mouth, and in fact there are no hard data to say that candy-like appearance is why a very young child chooses to investigate a consumable consumer product. It is quite likely that it may be even more important that the very young child sees his or her mother take that pill every day." Third, NDMA asserted that candy-like appearance is in the eye of the beholder and is simply too subjective a standard. It would be impossible to have an objective measure of candy-like appearance. Thus, NDMA stated that any provision for "no candy-like appearance" would not be practical and would be difficult to administer because of the subjective nature of assessing candy-like appearance.

The agency does not have data or other information specific to the question of how a candy-like appearance may contribute to the potential for an iron-containing supplement product to constitute a hazard to a young child. FDA's tentative view, however, is that it may not be possible to objectively measure the candy-like appearance of iron-containing products. Therefore, FDA requests comments on the use of "candy" and "colorful" coatings on iron-containing drugs and dietary supplements and information on whether these types of coatings make iron-containing products hazardous to infants and young children because of their apparent attractiveness. If the information received presents an objective basis for additional steps that FDA could take to limit the appeal of iron-containing products to young children, FDA will consider action in this regard.

B. Forms of Iron That May Be Less Toxic

NAS has reported that, during the period from 1970 to 1987, food manufacturers increased their use of elemental iron (i.e., finely divided metallic iron) by 120-fold and decreased their use of ferrous sulfate by 30 percent (Ref. 30). The increase in the use of elemental iron in conventional food may be attributed to its low cost and minimal reactivity in food. FDA is not aware of any reports of accidental ingestions or adverse reactions associated with the few commercially available iron-containing dietary supplements and drug products that incorporate elemental iron instead of an iron salt.

Three basic types of elemental iron powders are marketed for use in foods. The three types are reduced iron, electrolytic iron, and carbonyl iron. The term "carbonyl" refers to the production process, not the composition of the product. The bioavailability of these various elemental iron sources is dependent primarily on their physical characteristics, which in turn depend on the manufacturing method. For example, higher relative bioavailabilities of elemental iron are obtained with smaller particle sizes.

Some evidence suggests that carbonyl iron may be a useful substitute for the more commonly used chemical compounds of iron in reducing risk of accidental iron poisonings. Data from studies in animals suggest that carbonyl iron may be only 1/100th as toxic as ferrous sulfate in single doses, i.e., the LD_{50} (lethal dose for 50 percent of the test group) of ferrous sulfate is approximately 0.30 g Fe/kg (Ref. 32) and the LD_{50} for carbonyl iron is approximately 30.0 g Fe/kg body weight (Ref. 31). Thus, carbonyl iron, in comparison with ferrous sulfate, appears to have a much larger margin of safety between the level that would provide adequate iron nutrition and the level that causes acute toxicity. Consequently, carbonyl iron may be

inherently safer to use. At the same time, data from human subjects indicates that the overall bioavailability of carbonyl iron in supporting the nutritional functions of iron is about 70 percent that of ferrous sulfate (Ref. 31). Thus carbonyl iron is reasonably as effective in providing iron in the amounts needed to achieve the nutritive effects of iron. Its use may help to reduce the risk of iron poisoning in children.

FDA specifically requests comments on the appropriateness of elemental iron as a source of iron in drugs and dietary supplements, focusing on whether its use in iron-containing products would decrease the risk of pediatric poisonings while providing desirable iron nutrition to those who need iron supplementation. The agency is interested in receiving data on the potential of elemental iron for acute toxicity in humans and particularly in children.

FDA will carefully consider any information it receives on this subject. If the information is persuasive in establishing that the use of elemental iron would substantially decrease the risk of pediatric poisoning while allowing for effective dietary iron supplementation, FDA will consider exempting iron-containing products that incorporate elemental iron from any regulations that result from this rulemaking.

C. Educational Efforts

1. Review of Consumer Education Issues in Citizen Petitions

Two of the three petitions submitted discussed the benefits of educational efforts for the public and health professionals, focusing on the prevention of accidental pediatric iron poisoning. The AAPCC petition and the NDMA petition advocated educational efforts and outlined specific actions as described herein.

a. *The AAPCC petition.* The AAPCC petition called for the initiation of an FDA educational campaign for four different segments of the population. The four target segments are: (1) Parents, babysitters, daycare providers, and other consumers; (2) pediatricians; (3) obstetricians; and (4) other health professionals such as physicians, others who can prescribe iron, and pharmacists. The petition suggested that pediatricians discuss the dangers of an iron overdose with parents at the 6-month checkup, and that obstetricians inform mothers at the final postpartum checkup.

b. *The NDMA petition.* In the fall of 1993, NDMA in cooperation with CPSC, developed and launched a national consumer education campaign to be carried out in conjunction with the voluntary labeling and packaging measures (described above in section I.D. of this document) that were undertaken by the members of NDMA and NNFA. The purpose of the campaign, as stated in the petition, is to inform adults about how to protect children from accidental iron poisoning. The three major themes of the educational campaign mirror some of the messages in NDMA's and NNFA's voluntary warning statements for iron-containing products and are as follows:

(1) Adult awareness of the dangers to children if iron is accidentally swallowed in excess,

(2) Reclose the child-resistant package after every use, and,

(3) Keep iron-containing products out of the reach of children.

NDMA and CPSC began the educational campaign by distributing video and print news releases, radio news releases in English and Spanish, and public service announcements emphasizing the three-pronged message. The public service announcements are also being sent to consumer, health, and women's magazines.

2. Agency Response

FDA agrees with the petitioners that the public needs to be informed of the dangers of pediatric iron poisoning through public education efforts. Such efforts can be one important element in combating a cause of injury and deaths that has affected thousands of children over the last approximately 10 years. Thus, FDA commends NDMA and CPSC for their joint efforts in developing and distributing a national educational campaign targeting accidental iron poisoning, to coincide with the voluntary packaging and labeling measures for iron-containing products that have been undertaken by the members of NDMA and NNFA. FDA believes that the themes of this campaign are appropriate and are responsive to a fundamental need that exists for more awareness among adults of the dangers of pediatric iron poisoning and of the means to prevent these poisonings. Because of the seriousness of the problem, i.e., accidental iron ingestion is the leading cause of poisoning deaths among children, FDA intends to contribute to educating the public.

Accordingly, FDA is developing materials for a public information campaign that would address AAPCC's request and complement NDMA and CPSC's educational efforts by emphasizing the same awareness and prevention elements as the NDMA/CPSC campaign, as follows:

(1) Iron-containing products can seriously injure or even kill young children who accidentally swallow them.

(2) Reclose the child-resistant package completely and every time iron-containing products are opened.

(3) Keep all containers of iron-containing products out of reach of children *all the time.*

FDA's campaign will also address steps that should be taken by adults if an accidental ingestion of iron occurs:

(4) When children accidentally ingest iron-containing products, the attending person should quickly call a poison control center and follow their instructions, or take the child to an emergency room.

(5) Although the first symptoms, vomiting and diarrhea, may occur within 30 minutes, and these symptoms may be followed by an appearance of recovery, the child may still be in danger. Therefore, immediate professional consultation is critical.

The FDA materials will include print pieces available for distribution to different audiences, such as a backgrounder, a flyer, an *FDA Consumer* magazine article, and camera-ready newspaper columns. The *FDA Medical Bulletin*, which has 1,000,000 physician subscribers, is another vehicle that can be used to publicize this message.

The diversity of the audiences to be targeted by FDA's information campaign will include the AAPCC's suggested target populations. The FDA backgrounder will be a detailed handout for health professionals and consumer organizations. The flyer will be a short piece conveying the elements of FDA's message in a simple and concise manner for use in the home by parents, grandparents, and babysitters. The *FDA Consumer* article will reach the 23,000 subscribers to the magazine, a group that includes physicians and other health professionals, educators, reporters, and consumers. The camera-ready newspaper columns will be distributed to 10,000 smaller-circulation newspapers nationwide. In addition, FDA intends to provide information to consumer newsletter editors and consumers through "Dear Editor" letters and "Dear Consumer" letters about the efforts to prevent accidental pediatric iron poisoning.

Different offices in FDA, such as the Office of Public Affairs and the Office of Consumer Affairs, and offices of the Department of Health and Human Services will assist with the distribution of these materials. FDA intends to utilize its staff of public affairs

specialists to distribute these materials to the widely varied constituencies with whom these specialists frequently interact, such as other government agencies at the Federal, State, and local levels, advocacy organizations, trade associations, consumer groups, health professional organizations, and other interested groups.

V. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

A. Description of the Industry

There are approximately 300 iron-containing products that may be affected by these proposed actions, of which approximately one-half contain 30 mg or more iron per dosage unit. The types of iron-containing products that have been associated with poisonings of young children are products offered in solid oral dosage form as multi-vitamin/mineral supplements, products intended for use as iron supplements, and drug products. Typically, multi-vitamin/mineral supplements provide less than 30 mg of iron per dosage unit. Iron supplements and drug products typically contain 30 mg or more iron per dosage unit. The proposed action to require warning statements would affect all iron-containing products. On the other hand, FDA is proposing to require unit-dose packaging for products containing 30 mg or more iron per dosage unit. Therefore, most multi-vitamin/mineral supplements would be subject to the warning statement requirements but not to the packaging requirements. Most iron supplements and iron-containing drug products would be subject to both proposed requirements.

Iron-containing products may be purchased by consumers on their own initiative as dietary supplements, or they may be prescribed by physicians. The information available to the industry suggests that the overwhelming majority of iron- containing products are currently packaged in bottles (Ref. 33). Additional information suggests that iron-containing products administered in hospitals are commonly packaged in unit-dose packaging (Ref. 34). Unit-dose packaging is preferred by hospitals because with this type of packaging, each dosage unit has an identification and an expiration date, and the hospital can continue to use unit-dose packaged drugs rather than having to discard a bottle opened for a specific patient after that patient is discharged. Based on this information, FDA assumes that iron-containing products dispensed in hospitals are currently packaged in unit-dose packaging.

According to the National Center for Health Statistics, of the approximately 169 million persons of age 18 or older, 19.7 percent consume iron-containing products (Ref. 35). If it is assumed that each individual consumes one dosage unit per day,there are approximately 12 billion dosage units of iron- containing products consumed annually in the United States. The agency does not have complete information on the number of dosage units of iron-containing products that contain 30 mg or more iron. However, because only pregnant women require 30 mg/day, FDA assumes that the portion of higher-dosage iron-containing products can be estimated by the number of pregnant women in the United States. In 1991, the most recent year for which data are available, there were 4.1 million live births (Ref. 36). FDA is assuming a one-to-one correspondence between the number of live births and the number of pregnancies in concluding that there are about 4.1 million pregnant women on any one day in the United States. The number of live births may overestimate the number of pregnant women because multiple births by one woman are ignored. Also, the number of live births ignores pregnancies not resulting in a live birth, which may result in an underestimate of the number of pregnant women. If it is assumed that the number of live births is an estimate of the number of dosage units of products containing 30 mg or more iron, then the number of dosage units per year can be estimated at 4.1 million times 365 days per year or about 1.5 billion.

B. Regulatory Options

There are many possible regulatory alternatives available that may reduce the number of cases of pediatric poisonings from the accidental ingestion of iron-containing products. The options include packaging, warning statements, product reformulation, and educational efforts.

1. Packaging

One regulatory option available to FDA is to require that products containing iron be packaged in unit-dose containers. Because of the CPSC regulations, most iron-containing products currently must be packaged in CRC's. Therefore, the effect of this option would be to require child resistant unit-dose packaging for most of these products. FDA could require unit-dose packaging for all products or for only higher dosage products. For comparison, FDA will consider potencies of 30 mg, 40 mg, and 60 mg as the minimum potencies per dosage unit of iron that would trigger unit-dosage packaging.

a. *Costs.* There are four types of costs associated with a mandated packaging change: Equipment, materials, transportation, and administrative costs. If this option is selected, many packagers of iron-containing products will be required to purchase new packaging equipment. The cost of equipment used in packaging blisters, one common form of unit-dose packaging, is between $50,000 and $250,000, or on average $132,500. New equipment will not be purchased for each product sold because some manufacturers already possess unit-dose packaging equipment.

The cost of child-resistant bottles, currently the most common form of packaging, is approximately $7 per 1,000 dosage units. Child-resistant blisters cost approximately $9 per 1,000 dosage units, a difference of $2 per 1,000 dosage units.

FDA does not have information to estimate additional transportation costs caused by unit-dose packaging requirements and requests comments on increased transportation costs.

Additionally, firms are expected to incur administrative costs of approximately $500 per product in the first year. Administrative costs are the dollar value of the incremental

administrative effort expended in order to comply with a regulation. Administrative activities include, but are not limited to, identifying the underlying policy of the regulation, interpreting that policy relative to the firm's products, establishing a corporate position, formulating a method for compliance, and managing the compliance effort.

If FDA were to require unit-dose packaging for all iron- containing products irrespective of their potency per dosage unit, the cost of equipment would be $39 million (300 products × $132,500). The annual materials cost would be $24 million ((12 billion dosage units/1,000) × $2.00), or $260 million over the next 20 years (discounted at 7 percent). Administrative costs would be $150,000. Total costs associated with requiring unit- dose packaging for all iron-containing products would be $299 million over 20 years (discounted at seven percent).

If FDA were to require unit-dose packaging for products with 30 mg iron/dosage unit or higher, the cost of equipment would be $20 million (150 products × $132,500). The cost of materials would be $3 million per year or $32 million over 20 years (discounted at 7 percent). Administrative costs would be $75,000 (150 × $500). Total costs associated with requiring unit-dose packaging for products containing 30 mg or more per dosage unit would be $52 million over 20 years (discounted at 7 percent).

If FDA were to require unit-dose packaging for products with 40 mg iron/dosage unit or higher, the cost of equipment would be $13 million (100 products × $132,500). The cost of materials would be $2 million per year or $22 million over 20 years (discounted at 7 percent). Administrative costs would be $50,000 (100 × $500). Total costs associated with requiring unit-dose packaging for products containing 40 mg or more iron per dosage unit would be $35 million over 20 years (discounted at 7 percent).

If FDA were to require unit-dose packaging for products with 60 mg iron/dosage unit or higher, the cost of equipment would be $5 million (37 products × $132,500). The cost of materials would be $0.8 million per year or $8 million over 20 years (discounted at 7 percent). Administrative costs would be $19,000 (37 × $500). Total costs associated with requiring unit-dose packaging for products containing 60 mg or more iron per dosage unit would be $6 million over 20 years (discounted at 7 percent).

b. *Benefits.* In the past 7 years, there have been at least 37 cases of pediatric fatality from the accidental ingestion of iron-containing products, or a mean of 5.3 deaths per year. Data on the potency of the product consumed is available for 25 cases.

In all cases for which information is available, the product consumed contained at least 40 mg of iron. In the same 7-year period, there were nearly 190 poisonings reported that were life threatening or that resulted in permanent injury, and over 2,000 reported poisonings requiring some form of treatment. FDA believes that most, if not all, such deaths and some poisonings can be prevented by requiring that higher-potency iron-containing products be packaged in unit-dose packaging. Studies indicate that the child is less likely to consume the number of dosage units that may be fatal.

Although no studies have attempted to directly estimate the value of reducing the risk of death and illness to children in particular, many studies have attempted to estimate the value of reducing these risks to adults. Most of these estimates are based on wage differences between high and low risk jobs and, thus, are derived from the labor market decisions of middle-aged adults. Although these estimates cluster around a fairly small range, $2 million to $10 million, it is not clear that these estimates are valid when applied to children.

FDA has used estimates of the value of reducing risks to adults to a level that would avoid one statistical fatality between $1.5 million and $5 million in past rulemaking proceedings, including recent food labeling regulations and a current proposal to require domestic and foreign processors and importers of fish and fishery products to establish Hazard Analysis Critical Control Points (HAACP) controls to prevent the occurrence of hazards that could affect the safety of these seafood products (59 FR 4142, January 28, 1994). One method of estimating the value of reducing risks to children is to adjust the value of reducing risks to adults by accounting for the difference in the number of life-years saved. Under this approach, an often used estimate of the value of the risks to adults to a level that would avoid one statistical fatality is $5 million for a middle-aged adult. If this value does not vary with life years remaining (that is, if we assume that an infant is willing to pay the same amount to avoid risk of death as a 40-year old would be willing to pay and assuming the same distribution of wealth exists in both age groups), then $5 million is a reasonable estimate. If, however, this value does vary with life years remaining, then the corresponding value for reducing the risks to small children would be $11 million. FDA will use these figures ($5 to 11 million) to provide a range of estimates. Although FDA is using these values in this analysis, FDA stresses the tentative nature of these estimates and requests comments on an appropriate method of estimating the value of reducing risks to children.

The number of fatalities prevented by requiring unit-dose packaging for iron-containing products at any potency level less than 60 mg iron/dosage unit will not be significantly different. Because all fatalities for which FDA has information resulted from ingestion of dosage units of at least 40 mg iron potency, all three of these options (all products, 30 mg and above, and 40 mg and above) would result in benefits of reducing an average of 5.3 deaths per year, valued at between $280 million and $618 million over 20 years (discounted at 7 percent).

If, however, FDA were to select the option of requiring unit-dose packaging for all iron-containing products of potencies of 60 mg iron per dosage unit and above, an average of 5 deaths would be prevented per year leading to total discounted benefits of preventing fatalities over 20 years of between $265 million and $583 million.

Requiring unit-dosage packaging for iron-containing products will also reduce the number of nonfatal cases of pediatric iron poisoning. FDA has obtained from CPSC case reports for 78 iron ingestions necessitating emergency room treatment reported over 7 years, or an average of 11 illnesses per year. The potency of the product consumed was reported for 12 cases. In five of those cases, the potency reported was under 30 mg iron/dosage unit. In seven cases, the potency reported was over 60 mg iron/dosage unit. AAPCC data shows that from 1986 through 1992 there were nearly 190 reported poisonings that were life threatening or that resulted in permanent injury, and over 2,000 reported poisonings requiring some form of treatment as a result of accidental ingestion of adult and pediatric iron-containing products, or an average of 286 per year. FDA is unable to predict the percentage of these nonfatal poisonings which would be prevented by substituting unit-dose packaging for bottles. It is possible that not all nonfatal poisonings will be prevented because a child can still gain access to the product. However, he or she will gain access to fewer dosage units than if the product is in a bottle. FDA requests comments on this issue.

Using a methodology developed previously for FDA to value morbidity risks, FDA is able to estimate the value of reduced risk of nonfatal poisoning. By comparing similar symptoms and medical interventions, the agency has derived an estimate of the value of preventing a nonfatal pediatric iron poisoning of $20,000 per case. (Ref. 37) As stated previously, 7 out of 12 cases of nonfatal poisonings were a result of ingestion of products of potencies over 60 mg iron per dosage unit. If this proportion can be extrapolated to the remaining cases for which information is unknown, and if unit-dose packaging will prevent all nonfatal cases (at least 2,000 cases in 7 years), then requiring unit-dose packaging for products of 60 mg or more iron per dosage unit will add approximately $35 million to the benefits over the next 20 years (discounted at seven percent). Because no nonfatal cases for which information is known were a result of ingesting products with potencies between 30 mg and 60 mg iron per dosage unit, the options of requiring unit-dose packaging for products with potencies of 40 mg and 30 mg iron per dosage unit will not add more to the benefits than the previous option. Still assuming that all nonfatal cases can be prevented by unit-dose packaging, requiring packaging changes for all products would result in reduced morbidity valued at $61 million over the next 20 years.

The total value of the benefits of unit-dose packaging options is the sum of the value of reducing both mortality and morbidity risks. The selected option, requiring unit-dose packaging for all products containing 30 mg or more iron per dosage unit, would result in benefits of reducing mortality risks of between $280 million and $618 million and reduced morbidity valued at $61 million. Therefore, total discounted benefits of this option are between $315 million and $618 million. Table 7 summarizes the costs and benefits of the packaging options.

TABLE 10.—COSTS AND BENEFITS OF UNIT-DOSE PACKAGING OPTIONS

[In millions of dollars]

Trigger level	Total costs	Total benefits	Net benefits
All products	$299	$341 to 679	$42 to 380
>30 mg	52	315 to 653	263 to 601
>40 mg	35	315 to 653	280 to 618
>60 mg	6	300 to 618	294 to 612

2. Warning Labels

a. *Costs.* Every petition submitted to FDA requested that the agency require that iron-containing product labels contain warning statements about the potentially fatal effects of pediatric poisonings from accidental ingestion of iron-containing products. The cost associated with warning statements are the cost of redesigning the label, disposing of old labels, and administrative costs. In January, 1994, FDA published final rules regarding nutrition labeling of dietary supplements in accordance with the Nutrition Labeling and Education Act of 1990 (NLEA) and the Dietary Supplement Act of 1992. In its analysis of those rules (59 FR 352), FDA determined that the incremental cost of label changes for dietary supplement manufacturers is approximately $1,500 per label. FDA is proposing that the label warning statement be printed directly on the immediate container of the product, i.e., the container that holds the tablet or capsule, and on the principal display panel of the retail package, if such package is not the immediate container. If a product is sold in unit-dose packaging, the product would be required to bear the warning directly on each unit-dose package or on a strip of unit-dose packages in such a way that separating the unit-dose packages would not destroy the warning labeling. Manufacturers of all 300 iron-containing products will be required to change their labels on both the product container and the retail package to incorporate warning statements. However, because manufacturers of iron-containing products with 30 mg or more per dosage unit will also be required to change their packaging, they will not incur any incremental cost in adding a warning statement to the product container. Therefore, the labeling costs will be incurred by all 300 products for the retail package and for 150 products for the product container. The total cost would be a one-time cost of $675,000 (300 × 1.5 × $1,500).

An additional cost of this regulation may be an increase in iron deficiency anemia if susceptible adults react inappropriately to a warning label targeted for children. According to NHANES II, approximately 7.2 percent of females age 15 to 19 and 6.3 percent of females age 20 to 44 are iron-deficient but less than one-fourth of these women had anemia associated with the deficiency. In addition, males had a prevalence of less than 1 percent. FDA requests comments on this issue.

b. Benefits. Warning statements will only prevent pediatric iron poisonings to the extent that they lead to changes in the behavior of the adult controlling the use of the product (presumably the parent). Whether the warning messages prescribed in this proposed rule will cause a change in behavior will depend on a number of factors, including the degree to which the statement is noticed, read, and understood.

There is some evidence that warning statements can change behavior. For example, research indicates that rate of increase of sales of diet soft drinks declined after saccharin warnings were put on the labels of these products (Ref. 38). FDA is unable to predict exactly how many cases of pediatric iron poisoning will be prevented as a result of warning statements. To the extent that warning statements will cause adults to take proper care in handling iron-containing products, and to the extent that such care is not taken in the absence of warning statements, some cases of pediatric iron poisoning will be prevented.

If the agency requires unit-dose packaging, and this measure is 100 percent effective in preventing both fatal and nonfatal cases, then there are no benefits from warning labels on these products. However, for those products still packaged in bottles, warning labels may have an impact. If each nonfatal case of iron poisoning is valued at $20,000 and the one-time cost of warning statements is $675,000, then benefits of requiring warning statements will exceed costs if warning statements prevent at least three nonfatal cases every year for the next 20 years (discounted at 7 percent).

3. Product Reformulation—Appearance

Two petitions recommended product reformulation as a preventive measure. The petitions suggested that some adult formulations of iron-containing products look and taste like candy and thus are more appealing to children. The petitions stated that if the product were less appealing to children, the incidence of accidental ingestion would be reduced. The petition from NDMA urged FDA to reject reformulation for several reasons, including a lack of knowledge about what a pill looks like to a very young child, and about why the child is motivated to consume the product. The agency does not have information to determine either the costs or the benefits of reformulating the appearance of iron-containing products. Because reformulation costs are highly dependent on the individual decisions of firms, they are very difficult to estimate. Also, because there are currently no objective measures of the candy-like appearance of iron-containing products, the benefits are also difficult to determine.

4. Product Reformulation—Taste

Another possibility is to add a bitter substance to products containing iron which would discourage multiple ingestions. Such substances have been used in the past on products which discourage thumbsucking and nailbiting. It is highly likely that such a substance will not add significantly to the cost of producing iron-containing products. FDA requests information on a policy option that would require altering the taste of iron-containing products. Such information would include the potential substances that would make the pills bitter and data on their safety and whether this approach would be effective in preventing acute overdose of iron-containing products by children. FDA notes, however, that such an option may have the unintended side effect of causing persons who need iron supplementation to avoid the product. FDA requests information on both the costs and benefits of this option.

5. Forms of Iron that May be Less Toxic

As previously discussed in this document, some evidence suggests that carbonyl iron, an elemental iron powder, seems to be effective in the prevention or treatment of iron deficiency, and that it might be significantly less toxic than other forms of iron commonly used in iron-containing products. The agency requested data on the acute toxicity in humans, and particularly in children, of elemental iron. FDA stated that, if information is received that is persuasive that the use of elemental iron will substantially decrease the risk of pediatric poisoning while allowing for effective dietary iron supplementation, it will consider exempting iron-containing products that incorporate reduced iron from any regulations that result from this rulemaking. FDA does not have any information regarding the availability of such forms of iron for use in iron-containing products. Nor does FDA possess any information that would allow it to determine how many products would be reformulated with less toxic forms of iron in order to take advantage of such an exemption. FDA requests comment on the economic impact of exempting products containing less toxic forms of iron.

6. Consumer Education Campaign

Two of the three petitions that FDA received advocated educational efforts for the public and health professionals. FDA agrees that the public needs to be informed of the dangers of pediatric iron poisoning. The fact that in 7 years over 2,000 poisonings have occurred that have required some kind of treatment indicates that the public is not aware of the potential for serious harm or death in young children from accidental ingestion of iron-containing products. FDA is developing materials for a public information campaign utilizing the channels available to the agency.

7. Effective Dates

The agency is proposing to make any final rule that may issue based upon this proposal become effective 180 days after its publication in the **Federal Register**. FDA is requesting comments on this effective date. In general, costs of compliance for labeling and other requirements are less if longer compliance periods are provided because firms can incorporate mandatory changes to product, labeling, and packaging with regularly scheduled changes. FDA requests information on the ability of manufacturers of products that contain 30 mg or more iron per dosage unit to convert their packaging within the suggested compliance period.

C. Regulatory Flexibility

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses when possible. FDA is not aware that any small businesses will be affected by this proposed rule. Therefore, FDA tentatively concludes that this proposed rule will not result in a significant burden on small businesses. FDA requests comments on any potential adverse effect on small businesses.

D. Summary

FDA has examined the impact of the proposed rule in accordance with Executive Order 12866 and has determined that it is not an economically significant rule. The rule will result in total costs of approximately $53 million and discounted benefits of between $315 million and $653 million over the next 20 years (discounted at 7 percent).

FDA has also examined the impact of this proposed rule on small businesses in accordance with the Regulatory Flexibility Act. FDA is unaware of any iron-containing products manufactured by small businesses. Therefore, FDA has determined that this rule will not result in a significant burden on small businesses.

VII. Effective Date

The agency is proposing to make any final rule that may issue based upon this proposal became effective 180 days after its publication in the **Federal Register**. The agency is requesting comments on the proposed effective date. All comments concerning the effective date should be accompanied by data to support or justify any change in the proposed effective date.

VIII. Comments

The agency's intention in proposing this action is to reduce the incidence of pediatric iron poisonings from ingestion of iron-containing supplements and drug products. FDA has examined all relevant information available to the agency. The agency requests comments on this proposed action and is particularly interested in receiving comments that bear on the effectiveness of the proposed action to reduce the incidence of pediatric iron poisoning.

Interested persons may, on or before December 20, 1994, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Consumer Product Safety Commission, "Pediatric Iron Poisonings and Fatalities," p. 3, May 1994.

2. "Assessment of the Iron Nutritional Status of the U.S. Population Based on Data Collected in the Second National Health and Nutrition Examination Survey, 1976–1980," Federation of American Societies for Experimental Biology, Life Sciences Research Office, Bethesda, MD (under contract to FDA, Contract No. 223–83–2384, August 1984).

3. Subcommittee on the 10th Edition of the RDA's, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Recommended Dietary Allowances, 10th Ed." Washington, DC, National Academy Press, pp. 195–205, 1989.

4. Dawson, E. B., W. J. McGanity, "Protection of Maternal Iron Stores in Pregnancy," *The Journal of Reproductive Medicine*, 32:478–487, 1987.

5. Committee on the Prevention, Detection, and Management of Iron Deficiency Anemia Among U.S. Children and Women of Childbearing Age, Food and Nutrition Board, Institute of Medicine, "Iron Deficiency Anemia: Recommended Guidelines for the Prevention, Detection, and Management Among U.S. Children and Women of Childbearing Age," by Earl R. and C. E. Woteki, (editors) National Academy Press, Washington, DC, pp. 17–18, 1993.

6. "Iron," in *Rudolph's Pediatrics*, A. Rudolph, J.I.E. Hoffman, C. D. Rudolph, editors; Appleton & Lange, Norwalk, CT, 19th ed., p. 806, 1991.

7. "Iron," in *Nelson Textbook of Pediatrics*, by R. E. Behrman, R. M. Kliegman, W. E. Nelson, and V. C. Vaughan (editors), W.B. Saunders Co., Philadelphia, PA, 14th ed., pp. 1780–1781, 1992.

8. "Iron," in *Manual of Toxicology Emergencies*, Noji, K. (editor), by Year Book Medical Publishers, Inc., pp. 496–506, 1989.

9. "Hematopoietic Agents: Growth Factors, Minerals, and Vitamins," in *The Pharmacological Basis of Therapeutics*, edited by A. G. Gilman, T. W. Rall, A. S. Nies, P. Taylor (editors), Pergamon Press, Elmsford, New York, 8th ed., pp. 1291, 1990.

10. Troendle, G., FDA memorandum, July 12, 1994.

11. Temeck, J., FDA memorandum, August 10, 1994.

12. American Association of Poison Control Center, Inc., petition to FDA, 91P–0186/CP1, 1991.

13. Attorneys General Petition to FDA, 93P–0306/CP1, 1993.

14. Litovitz, T.L., T.G. Martin, B. Schmitz, "1986 Annual Report of the American Association of Poison Control Centers National Data Collection System," *American Journal of Emergency Medicine*, 5:405–445, 1987.

15. Litovitz, T. L., B. Schmitz, N. Matyunas, T. G. Martin, "1987 Annual Report of the American Association of Poison Control Centers National Data Collection System," *American Journal of Emergency Medicine*, 6:479–515, 1988.

16. Litovitz, T. L., B. Schmitz, K. C. Holm, "1988 Annual Report of the American Association of Poison Control Centers National Data Collection System," *American Journal of Emergency Medicine*, 7:495–545, 1989.

17. Litovitz, T. L., B. Schmitz, K. M. Bailey, "1989 Annual Report of the American Association of Poison Control Centers National Data Collection System," *American Journal of Emergency Medicine*, 8:394–442, 1990.

18. Litovitz, T. L., K. M. Bailey, B. Schmitz, K. C. Holm, W. Klein-Schwartz, "1990 Annual Report of the American Association of Poison Control Centers National Data Collection System," *American Journal of Emergency Medicine*, 9:461–509, 1991.

19. Litovitz, T. L., K. C. Holm, K. M. Bailey, B. F. Schmitz, "1991 Annual Report of the American Association of Poison Control Centers National Data Collection System," American Journal of Emergency Medicine, 10:452–505, 1992.

20. Litovitz, T. L., K. C. Holm, C. Clancy, B. F. Schmitz, L. R. Clark, G. M. Oderda, "1992 Annual Report of the American Association of Poison Control Centers National Data Collection System," *American Journal of Emergency Medicine*, 11:494–555, 1993.

21. U.S. Consumer Product Safety Commission iron fatality case reports.

22. U.S. Consumer Product Safety Commission iron poisoning emergency room followup case reports.

23. Nonprescription Drug Manufacturers Association Petition to FDA, 93P–0306/CP2.

24. Stewart, D. W. and I. M. Martin, "Intended and Unintended Consequences of Warning Messages: A Review and Synthesis of Empirical Research," *Journal of Public Policy and Marketing*, 13(1):1–19, 1994.

25. Breault, H. J. "Five Years with 5 Million Child-Resistant Containers," *Clinical Toxicology*, 7(1):91–95, 1974.

26. Wilbur, C. J., "Child Resistant Effectiveness Conventional Pouch Packaging (Non-Child Resistant)," U.S. Consumer Product Safety Commission, C–805–9864, 1978.

27. Wilbur, C. J., "Child Resistant Effectiveness Conventional Blister Card Packaging (Non-Child Resistant," U.S. Consumer Product Safety Commission, E–850–3006, 1978.

28. Wilbur, C. J., "Closure Testing Equipment (CTE) Studies Non-Child Resistant (NCR) Snap Type Packaging, U.S. Consumer Product Safety Commission, 1990.

29. Wilbur, C. J., "Closure Testing Equipment (CTE) Studies Non-Child Resistant (NCR) Continuous Threaded Type Packaging," U.S. Consumer Product Safety Commission, 1990.

30. Whittaker, P., V. C. Dunkel, "Iron, Magnesium and Zinc Fortification of Food," in *Handbook on Metal-Ligand Interactions of Biological Fluids: Metal-Ligand Interactions in Human Biology and Medicine*, vol. 2, by G. Berthon (editor), Marcel Dekker, Inc., New York, New York, pp. 1–12, 1994.

31. Devasthali, S. D., V. R. Gordeuk, G. M. Brittenham, J. R. Bravo, M. A. Hughes, and L. J. Keating, "Bioavailability of Carbonyl Iron: A Randomized, Double-Blind Study," *European Journal of Haematolgy*, 46:272–278, 1991.

32. The Merck Index, "An Encyclopedia of Chemicals, Drugs, and Biologicals," S. Budavari, M. J. O'Neil, A. Smith, and P. E. Heckelman (editors), Merck and Co., Inc., Rahway, New Jersey, 11th ed., pp. 635, 1989.

33. Memoranda of telephone conversations between Peter Mayberry, Health Care Compliance Packaging Council, and Elizabeth Ann Cox, FDA, dated May 31 and June 8, 1994.

34. Memoranda of telephone conversations between Tom McGinnis, Office of Health Affairs, FDA and Elizabeth Ann Cox, FDA, dated August 3 and 15, 1994.

35. National Center for Health Statistics, "Use of Vitamin and Mineral Supplements in the United States: Current Usere, Types of Products, and Nutrients." U.S. Department of Health and Human Services, 174:1–19, 1989.

36. U.S. Bureau of the Census, 1993, Statistical Abstract of the United States: 1993 (113th Ed.), page 73; Government Printing Office, Washington, DC 20402.

37. RTI, "Estimating the Value of Consumers' Loss from Foods Violating the FD&C Act," FDA Contract No. 233–86–2097, Project Officer—Richard A. Williams, Jr., Research Triangle Park, NC, September 1988.

38. Orwin, R. G., R. E. Schucker, and R. C. Stokes, "Evaluating the Life Cycle of a Product Warning: Saccharin and Diet Soft Drinks, *Evaluation Review*, 8 (6), 801–822, 1984.

List of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 101, 170, and 310 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.17 is amended by adding a new paragraph (e) to read as follows:

§ 101.17 Food labeling warning and notice statements.

* * * * *

(e) Dietary supplements containing iron or iron salts. (1) The labeling of any dietary supplement in solid oral dosage form (e.g., tablets or capsules) that contains iron or iron salts for use as an

iron source shall bear the following statement:

(i) If the product is packaged in unit-dose packaging as defined in § 170.55 of this chapter:

WARNING—Keep away from children. Keep in original package until each use. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(ii) If the product contains less than 30 milligrams of iron per dosage unit and is packaged by the manufacturer in other than unit-dose packaging as defined in § 170.55 of this chapter, e.g., a container with a child-resistant closure, its label shall bear the following statement:

WARNING—Close tightly and keep away from children. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(2) The statement required by paragraph (e)(1)(i) of this section shall appear prominently and conspicuously on the immediate container labeling in such a way that the warning is intact until all of the dosage units to which it applies are used. The statement required by paragraph (e)(1)(ii) of this section shall appear prominently and conspicuously on the immediate container labeling. In all cases where the immediate container is not the retail package, the warning statement shall also appear prominently and conspicuously on the principal display panel of the retail package. In addition, the warning statement shall appear on any labeling that contains warnings.

PART 170—FOOD ADDITIVES

3. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

4. New § 170.55 is added to subpart C to read as follows:

§ 170.55 Iron and iron salts in dietary supplements not in conventional food form.

The use of iron and iron salts as iron sources in dietary supplements is safe, or generally recognized as safe, only when the package in which the supplements are sold is labeled in accordance with § 101.17(e) of this chapter and, if the dietary supplements are offered in solid oral dosage form (e.g., tablets or capsules) and contain 30 milligrams or more of iron per dosage unit, when such supplements are packaged in unit-dose packaging. "Unit-dose packaging" means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term "dosage unit" means the individual physical unit of the product, e.g., tablets or capsules.

PART 310—NEW DRUGS

5. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

6. New § 310.518 is added to subpart E to read as follows:

§ 310.518 Drug products containing iron or iron salts.

Drug products containing elemental iron or iron salts as an active ingredient in solid oral dosage form, e.g., tablets or capsule shall meet the following requirements:

(a) *Packaging.* If the product contains 30 milligrams or more of iron per dosage unit, it shall be packaged in unit-dose packaging. "Unit-dose packaging" means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term "dosage unit" means the individual physical unit of the product (e.g., tablets or capsules).

(b) *Labeling.* (1) If the product is packaged by the manufacturer in unit-dose packaging, its label shall bear the following statement:

WARNING—Keep away from children. Keep in original package until each use. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(2) If the product contains less than 30 milligrams of iron and is packaged by the manufacturer in other than unit-dose packaging, e.g., a container with a child-resistant closure, its label shall bear the following statement:

WARNING—Close tightly and keep away from children. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(3) The statement required by paragraph (b)(1) of this section shall appear prominently and conspicuously on the immediate container labeling in such a way that the warning is intact until all of the dosage units to which it applies are used. The statement required by paragraph (b)(2) of this section shall appear prominently and conspicuously on the immediate container labeling. In all cases where the immediate container is not the retail package, the warning statement shall also appear prominently and conspicuously on the principal display panel of the retail package. In addition, the warning statement shall appear on any labeling that contains warnings.

Dated: September 28, 1994.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 94–24476 Filed 10–4–94; 4:30pm]

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federal register

Thursday
October 6, 1994

Part V

Department of Transportation

Federal Highway Administration

Truck Size and Weight; Vehicle Size and Weight Limits in Metric Units; Notice

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. 94–20]

Truck Size and Weight; Vehicle Size and Weight Limits in Metric Units

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of interpretation; opportunity for comments.

SUMMARY: The FHWA has initiated a phased 5-year plan to convert its activities and business operations to the Metric System of Measurements as required by the 1988 amendments to the Metric Conversion Act of 1975. Details of the FHWA metric conversion policy and plan were published in the **Federal Register** on June 11, 1992 (57 FR 24843). The plan calls for the conversion to be completed by September 30, 1996. FHWA regulations currently specify vehicle size and weight limits and certain distances in English units. This notice converts the most commonly used of these units to their metric equivalents and provides guidance for the public to make similar conversions.

DATES: Comments on this interpretation should be submitted by January 4, 1995.

ADDRESSES: Submit written, signed comments to the FHWA Docket No. 94–20, Room 4232, HCC–10, Office of Chief Counsel, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Klimek, Office of Motor Carrier Information Management, (202) 366–2212 or Mr. Charles Medalen, Office of the Chief Counsel, (202) 366–1354, Federal Highway Administration, Department of Transportation, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: The English unit values for Federal size (length and width) and weight limits are set by law (49 U.S.C. app. 2311, 2316 and 23 U.S.C. 127, respectively). The conversion of these values to metric equivalents is not intended to change the law. However, public acceptance of the metric system will be considerably delayed unless regulatory limits are reasonably easy to use, remember, and enforce.

The Congress enacted the current single-axle, tandem-axle, and gross weight limits—20,000, 34,000, and 80,000 pounds, respectively—for economic and engineering reasons, but it obviously chose round numbers to promote compliance and ease of enforcement. That policy is also embodied in the Bridge Formula, where calculated weights must be rounded to the nearest 500 pounds [23 U.S.C. 127(a)], producing a weight table with increments of exactly 500 or 1,000 pounds. In other words, the legal limit could be nearly 250 pounds higher or lower than the figure generated by the formula. The Congress balanced its interest in establishing precise and accurate weight limits with the need to make a complex proposal more workable. Similarly, the FHWA believes that some compromises are necessary to reconcile the statutory mandates to enforce size and weight limits denominated in English units with the goal to promote conversion of all measurements to the metric system.

Consider, for example, the maximum weight for a tandem axle, 34,000 pounds. The precise metric equivalent is 15,422.4 kilograms. Converting to a fractional value is obviously impractical, and the nearest whole kilogram is an awkward number also. One kilogram represents 65 ten-thousandths of 1 percent (.0065 percent) of 15,422 kilograms. In an industry where scales are considered acceptable if they are accurate to within 0.2 percent, 1 kilogram has little meaning. Similarly, a 48-foot trailer is 14.6304 meters long. Enforcement officers are not in a position to measure ten-thousandths of a meter, but all Metric devices for measuring length are calibrated in hundredths of a meter.

With this in mind, the FHWA has decided, for purposes of enforcing Federal weight law, to allow the rounding of weight values up or down to the nearest whole number of kilograms evenly divisible by 10; this gives a margin of error of about 5 kilograms. In the example above, the 15,422.4 kilogram tandem-axle limit would, therefore, be rounded down to 15,420 kilograms. Five kilograms, just over 11 pounds, are well within the 0.1 percent margin of error allowed by the National Institute of Standards and Technology for a new certified truck scale. Such a scale could have a margin of error of 20 pounds when weighing a 20,000-pound single axle, 34 pounds when weighing a 34,000-pound tandem axle, and proportionally more for heavier loads. The FHWA believes that this conversion standard will ease the transition to the metric system while ensuring that the weight standards established by the Congress are enforced. We anticipate that implementation of this conversion standard will have no effect on current loading and enforcement practices, as no change in current weight regulations is intended.

The FHWA also will allow the measurement of dimensional values to the nearest one-hundreth of a meter. A 48-foot trailer, therefore, would be 14.63 meters long. Since dimensions do not fluctuate like vehicle weights, the FHWA anticipates fewer problems in enforcing these limits. The rule establishing a vehicle width of 2.6 meters as the legal equivalent of 102 inches, 23 CFR 658.15(a) remains unchanged.

The metric weight table (appendix A) yields values more precise than those resulting from the rounding method described in this notice. For example, the table shows that a three-axle vehicle with a 32-foot (or 9.75 meter) wheelbase has a gross weight limit of 27,216 kilograms; States may round this figure to 27,220 kilograms. The values in the table have not been rounded, however, because the FHWA will not require States to further round Federal weight standards if they choose not to do so. The metric values in the table represent the conversion of English units which have already been rounded one time as discussed earlier.

This notice supersedes the FHWA's previous policy. In a May 16, 1994, letter to the Florida Department of Transportation, which was transmitted to the other States, the Associate Administrator for Motor Carriers announced that the Agency intended "to use as precise conversions as possible to determine the metric equivalent to the English unit." After further consideration, the FHWA has determined that the rounding methods described above are consistent with the requirements of Federal law and will reduce the difficulties inherent in switching from English to metric units.

With regard to terminology, the FHWA is aware that the correct technical equivalent for an English "weight" limit would be a metric "mass" limit. However, because of its historic and widespread use, the term "weight limits," when referring to commercial motor vehicles, will be retained for the present time.

The FHWA will use the following conversion factors, as established by the American Society for Testing and Materials (ASTM) in its Standard ASTM E380, "Standard Practice for Use of the

SI International System of Units," to arrive at metric equivalent measurements:

Weight	Distance and dimensions
1 pound = 0.4536 kilograms.	1 mile = 1.609 kilometers.
1 Metric ton = 2,205 pounds.	1 foot = 0.3048 meters.
1 Metric ton = 1,000 kilograms.	1 inch = 25.4 millimeters.

Conversion and Rounding

When converting mixed size or weight units, e.g., feet and inches, to the metric equivalent, reduce the measurement to the smaller unit before converting to metric and rounding. For example, 10 feet, 3 inches equals 123 inches; 123 inches multiplied by 25.4 millimeter/inch equals 3,124.2 millimeters; round to 3120 millimeters or 3.12 meters.

Converting Part 658 to Metric Measurements

The metric equivalent of every English unit of measurement which is used in 23 CFR part 658 and which applies in all States is provided in the following table:

CONVERSIONS OF WEIGHT QUANTITIES

Quantity	Metric equivalent
1 lb	0.4536 kg.
1,000 lbs	450 kg.
20,000 lbs	9,070 kg.
34,000 lbs	15,420 kg.
80,000 lbs	36,290 kg.

CONVERSIONS OF DIMENSIONAL QUANTITIES

Quantity	Metric equivalent
3 inches	76 millimeters.
27 inches	0.69 meters.
3 feet	0.91 meters.
40 inches	1.02 meters.
4 feet	1.22 meters.
96 inches	2.44 meters.
102 inches	2.6 meters.*
108 inches	2.74 meters.
12 feet	3.66 meters.
28 feet	8.53 meters.
28.5 feet	8.69 meters.
34 feet	10.36 meters.
36 feet	10.97 meters.
41 feet	12.5 meters.
45 feet	13.72 meters.
48 feet	14.63 meters.
60 feet	18.29 meters.
65 feet	19.81 meters.
75 feet	22.86 meters.

*An exception to the standard conversion process established by 23 CFR 658.15(a).

OTHER CONVERSIONS

Quantity	Metric equivalent
1 mile	1.61 km.
500 pounds per inch	8930 kg/m.

Metric Equivalent of the Federal Bridge Formula

The Federal Bridge Formula found in 23 U.S.C. 127 is an integral part of the limits placed on vehicle weight. The Bridge Formula in English units is as follows:

$$W = 500\left[\frac{LN}{N-1} + 12N + 36\right]$$

W=The maximum weight in pounds that can be carried on a group of two or more axles to the nearest 500 pounds.

L=The distance in feet between the outer axles of any two or more consecutive axles.

N=The number of axles being considered.

Because the statute requires the use of English units to calculate Bridge Formula limits, a metric formula is not really possible. However, appendix A reproduces in English and the equivalent metric units the weight table generated by the Bridge Formula. The values in this table reflect the FHWA's policy of rounding down when calculated weights fall exactly halfway between 500-pound increments. Because the Bridge Formula is designed to protect the highway infrastructure, the agency has determined that this conservative policy is consistent with the statutory mandate.

Congress decided to adopt the metric system nearly 20 years ago. A notice of proposed rulemaking would serve no purpose since conversion to that standard is the policy of the United States. There may be errors in the data published in this notice, however, and the FHWA has therefore established a docket to receive technical comments on these provisions. The interpretations will be corrected as necessary, and in case of omissions, consideration will be given to additional interpretations.

(Sec. 123, Pub. L. 95–599, 92 Stat. 2701; 23 U.S.C. 127, 141, and 315; 49 U.S.C. 31111–31114; and 49 CFR 1.48.

Issued on: September 30, 1994.

Rodney E. Slater,

Federal Highway Administrator.

Based on weight formula $W = 500\left[\frac{LN}{N-1} + 12N + 36\right]$

APPENDIX A—PERMISSIBLE GROSS LOADS FOR VEHICLES IN REGULAR OPERATION [1]

Distance in feet (L) (column 1) and meters (m) (column 2) between extremes of any group of 2 or more consecutive axles		Maximum load in pounds (lb) and kilograms (kg) carried on any group of 2 or more consecutive axles [2]							
Column 1	Column 2	Axles		3 Axles		4 Axles		5 Axles	
		lb	kg	lb	kg	lb	kg	lb	kg
4	1.22	34,000	15,422	.....	.....	.....	.....	.....	.....
5	1.52	34,000	15,422	.....	.....	.....	.....	.....	.....
6	1.83	34,000	15,422	.....	.....	.....	.....	.....	.....
7	2.13	34,000	15,422	.....	.....	.....	.....	.....	.....
8	2.44	34,000	15,422	34,000	15,422	.....	.....	.....	.....
8.01	2.44	38,000	17,237	42,000	19,051	.....	.....	.....	.....
9	2.74	39,000	17,690	42,500	19,278	.....	.....	.....	.....
10	3.05	40,000	18,144	43,500	19,732	.....	.....	.....	.....
11	3.35	.....	.....	44,000	19,958	.....	.....	.....	.....
12	3.66	.....	.....	45,000	20,412	50,000	22,680	.....	.....

Column 1	Column 2	Axles		3 Axles		4 Axles		5 Axles	
		lb	kg	lb	kg	lb	kg	lb	kg
13	3.96	.....	.....	45,500	20,639	50,500	22,907	.....	.....
14	4.27	.....	.....	46,500	21,092	51,500	23,360	.....	.....
15	4.57	.....	.....	47,000	21,319	52,000	23,587	.....	.....
16	4.88	.....	.....	48,000	21,773	52,500	23,814	58,000	26,309
17	5.18	.....	.....	48,500	22,000	53,500	24,268	58,500	26,536
18	5.49	.....	.....	49,500	22,453	54,000	24,494	59,000	26,762
19	5.79	.....	.....	50,000	22,680	54,500	24,721	60,000	27,216
20	6.10	.....	.....	51,000	23,134	55,500	25,175	60,500	27,443
21	6.40	.....	.....	51,500	23,360	56,000	25,402	61,000	27,670
22	6.71	.....	.....	52,500	23,814	56,500	25,628	61,500	27,896
23	7.01	.....	.....	53,000	24,041	57,500	26,082	62,500	28,350
24	7.32	.....	.....	54,000	24,494	58,000	26,309	63,000	28,577
25	7.62	.....	.....	54,500	24,721	58,500	26,536	63,500	28,804
26	7.92	.....	.....	55,500	25,175	59,500	26,989	64,000	29,030
27	8.23	.....	.....	56,000	25,402	60,000	27,216	65,000	29,484
28	8.53	.....	.....	57,000	25,855	60,500	27,443	65,500	29,711
29	8.84	.....	.....	57,500	26,082	61,500	27,896	66,000	29,938
30	9.14	.....	.....	58,500	26,536	62,000	28,123	66,500	30,164
31	9.45	.....	.....	59,000	26,762	62,500	28,350	67,500	30,618
32	9.75	.....	.....	60,000	27,216	63,500	28,804	68,000	30,845
33	10.06	.....	.....	.....	.....	64,000	29,030	68,500	31,072
34	10.36	.....	.....	.....	.....	64,500	29,257	69,000	31,298
35	10.67	.....	.....	.....	.....	65,500	29,711	70,000	31,752
36	10.97	.....	.....	.....	.....	66,000	29,938	70,500	31,979
37	11.28	.....	.....	.....	.....	66,500	30,164	71,000	32,206
38	11.58	.....	.....	.....	.....	67,500	30,618	71,500	32,432
39	11.89	.....	.....	.....	.....	68,000	30,845	72,500	32,886
40	12.19	.....	.....	.....	.....	68,500	31,072	73,000	33,113
41	12.50	.....	.....	.....	.....	69,500	31,525	73,500	33,340
42	12.80	.....	.....	.....	.....	70,000	31,752	74,000	33,566
43	13.11	.....	.....	.....	.....	70,500	31,979	75,000	34,020
44	13.41	.....	.....	.....	.....	71,500	32,432	75,500	34,247
45	13.72	.....	.....	.....	.....	72,000	32,659	76,000	34,474
46	14.02	.....	.....	.....	.....	72,500	32,886	76,500	34,700
47	14.33	.....	.....	.....	.....	73,500	33,340	77,500	35,154
48	14.63	.....	.....	.....	.....	74,000	33,566	78,000	35,381
49	14.94	.....	.....	.....	.....	74,500	33,793	78,500	35,608
50	15.24	.....	.....	.....	.....	75,500	34,247	79,000	35,834
51	15.54	.....	.....	.....	.....	76,000	34,474	80,000	36,288
52	15.85	.....	.....	.....	.....	76,500	34,700	80,500	36,515
53	16.15	.....	.....	.....	.....	77,500	35,154	81,000	36,742
54	16.46	.....	.....	.....	.....	78,000	35,381	81,500	36,968
55	16.76	.....	.....	.....	.....	78,500	35,608	82,500	37,422
56	17.07	.....	.....	.....	.....	79,500	36,061	83,000	37,649
57	17.37	.....	.....	.....	.....	80,000	36,288	83,500	37,876
58	17.68	.....	.....	.....	.....	.....	.....	84,000	38,102
59	17.98	.....	.....	.....	.....	.....	.....	85,000	38,556
60	18.29	.....	.....	.....	.....	.....	.....	85,500	38,783

Column 1	Column 2	6 Axles		7 Axles		8 Axles		9 Axles	
		lb	kg	lb	kg	lb	kg	lb	kg
61	18.59	90,500	41,051	95,500	43,319	101,000	45,814	106,500	48,308
62	18.90	91,000	41,278	96,000	43,546	101,500	46,040	107,000	48,535
63	19.20	92,000	41,731	96,500	43,772	102,000	46,267	107,500	48,762
64	19.51	92,500	41,958	97,500	44,226	102,500	46,494	108,000	48,989
65	19.81	93,000	42,185	98,000	44,453	103,000	46,721	108,500	49,216
66	20.12	93,500	42,412	98,500	44,680	103,500	46,948	109,000	49,442
67	20.42	94,000	42,638	99,000	44,906	104,500	47,401	109,500	49,669
68	20.73	95,000	43,092	99,500	45,133	105,000	47,628	110,000	49,896
69	21.03	95,500	43,319	100,000	45,360	105,500	47,855	111,000	50,350
70	21.34	96,000	43,546	101,000	45,814	106,000	48,082	111,500	50,576
71	21.64	96,500	43,772	101,500	46,040	106,500	48,308	112,000	50,803
72	21.95	97,000	43,999	102,000	46,267	107,000	48,535	112,500	51,030
73	22.25	98,000	44,453	102,500	46,494	107,500	48,762	113,000	51,257
74	22.56	98,500	44,680	103,000	46,721	108,500	49,216	113,500	51,484
75	22.86	99,000	44,906	103,500	46,948	109,000	49,442	114,000	51,710
76	23.16	99,500	45,133	104,500	47,401	109,500	49,669	114,500	51,937
77	23.47	100,000	45,360	105,000	47,628	110,000	49,896	115,500	52,391
78	23.77	101,000	45,814	105,500	47,855	110,500	50,123	116,000	52,618
79	24.08	101,500	46,040	106,000	48,082	111,000	50,350	116,500	52,844
80	24.38	102,000	46,267	106,500	48,308	111,500	50,576	117,000	53,071

Column 1	Column 2	6 Axles		7 Axles		8 Axles		9 Axles	
		lb	kg	lb	kg	lb	kg	lb	kg
81	24.69	102,500	46,494	107,000	48,535	112,500	51,030	117,500	53,298
82	24.99	103,000	46,721	108,000	48,989	113,000	51,257	118,000	53,525
83	25.30	104,000	47,174	108,500	49,216	113,500	51,484	118,500	53,752
84	25.60	104,500	47,401	109,000	49,442	114,000	51,710	119,000	53,978
85	25.91	105,000	47,628	109,500	49,669	114,500	51,937	120,000	54,432
86	26.21	105,500	47,855	110,000	49,896	115,000	52,164	120,500	54,659
87	26.52	106,000	48,082	110,500	50,123	115,500	52,391	121,000	54,886
88	26.82	107,000	48,535	111,500	50,576	116,500	52,844	121,500	55,112
89	27.13	107,500	48,762	112,000	50,803	117,000	53,071	122,000	55,339
90	27.43	108,000	48,989	112,500	51,030	117,500	53,298	122,500	55,566
91	27.74	108,500	49,216	113,000	51,257	118,000	53,525	123,000	55,793
92	28.04	109,000	49,442	113,500	51,484	118,500	53,752	123,500	56,020
93	28.35	110,000	49,896	114,000	51,710	119,000	53,978	124,500	56,473
94	28.65	110,500	50,123	115,000	52,164	119,500	54,205	125,000	56,700
95	28.96	111,000	50,350	115,500	52,391	120,500	54,659	125,500	56,927
96	29.26	111,500	50,576	116,000	52,617	121,000	54,886	126,000	57,154
97	29.57	112,000	50,803	116,500	52,844	121,500	55,112	126,500	57,380
98	29.87	113,000	51,257	117,000	53,071	122,000	55,339	127,000	57,607
99	30.18	113,500	51,484	117,500	53,298	122,500	55,566	127,500	57,834
100	30.48	114,000	51,710	118,500	53,752	123,000	55,793	128,000	58,061
101	30.78	114,500	51,937	119,000	53,978	123,500	56,020	129,000	58,514
102	31.09	115,000	52,164	119,500	54,205	124,500	56,473	129,500	58,741
103	31.39	116,000	52,618	120,000	54,432	125,000	56,700	130,000	58,968
104	31.70	116,500	52,844	120,500	54,659	125,500	56,927	130,500	59,195
105	32.00	117,000	53,071	121,000	54,886	126,000	57,154	131,000	59,422
106	32.31	117,500	53,298	122,000	55,339	126,500	57,380	131,500	59,648
107	32.61	118,000	53,525	122,500	55,566	127,000	57,607	132,000	59,875
108	32.92	119,000	53,978	123,000	55,793	127,500	57,834	132,500	60,102
109	33.22	119,500	54,205	123,500	56,020	128,500	58,288	133,500	60,556
110	33.53	120,000	54,432	124,000	56,246	129,000	58,514	134,000	60,782
111	33.83	120,500	54,659	124,500	56,473	129,500	58,741	134,500	61,009
112	34.14	121,000	54,886	125,500	56,927	130,000	58,968	135,000	61,236
113	34.44	122,000	55,339	126,000	57,154	130,500	59,195	135,500	61,463
114	34.75	122,500	55,566	126,500	57,380	131,000	59,422	136,000	61,690
115	35.05	123,000	55,793	127,000	57,607	131,500	59,648	136,500	61,916
116	35.36	123,500	56,020	127,500	57,834	132,500	60,102	137,000	62,143
117	35.66	124,000	56,246	128,000	58,061	133,000	60,329	138,000	62,597
118	35.97	125,000	56,700	129,000	58,514	133,500	60,556	138,500	62,824
119	36.27	125,500	56,927	129,500	58,741	134,000	60,782	139,000	63,050
120	36.58	126,000	57,154	130,000	58,968	134,500	61,009	139,500	63,277

[1] The permissible loads are computed to the nearest 500 pounds as required by statute.
[2] The following loaded vehicle must not operate over H15–44 bridges: 3–S2 (5-axle) with wheelbase less than 38 feet (11.58 meters); 2–S1–2 (5-axle) with wheelbase less than 45 feet (13.72 meters); 3–3 (6-axle) with wheelbase less than 45 feet; and 7-, 8-, and 9-axle vehicles regardless of wheelbase.

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Thursday
October 6, 1994

Part VI

Department of the Treasury

Office of Foreign Assets Control

31 CFR Part 580

Haitian Transactions Regulations; Suspension of Unilateral Sanctions; Final Rule

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 580

Haitian Transactions Regulations; Suspension of Unilateral Sanctions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendments.

SUMMARY: In light of the pending restoration of the democratically-elected government of Haiti, the Treasury Department is amending the Haitian Transactions Regulations to suspend unilateral U.S. sanctions with respect to Haiti, including unblocking the property of most Haitian nationals resident in Haiti, terminating the prohibition on most financial transfers between Haiti and the United States, and terminating a ban on the entry of certain vessels into U.S. ports. The amendment further generally authorizes exports to Haiti of food and food products, and announces the availability of specific licenses for certain humanitarian, journalistic, and other transactions in conformity with United Nations sanctions.

EFFECTIVE DATE: October 5, 1994.

FOR FURTHER INFORMATION CONTACT: John T. Roth, Chief of Policy Planning and Program Management (tel.: 202/622-2500), Steven I. Pinter, Chief of Licensing (tel.: 202/622-2480), or William B. Hoffman, Chief Counsel (tel.: 202/622-2410), Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document is available as an electronic file on *The Federal Bulletin Board* the day of the publication in the **Federal Register**. By modem dial 202/512-1387 or call 202/515-1530 for disks or paper copies. This file is available in Postscript, WordPerfect 5.1 and ASCII.

Background

On March 31, 1992, the Department of the Treasury promulgated the Haitian Transactions Regulations, 31 CFR part 580 (the "Regulations"), in consultation with the Department of State, to implement the President's Executive Orders No. 12775 of October 4, 1991, declaring a national emergency with respect to Haiti and ordering specified measures against Haiti, and No. 12779 of October 28, 1991, ordering a trade embargo against Haiti. Since the Regulations were published, the President has issued 6 additional Executive orders: Executive Orders No. 12853 of June 30, 1993, "Blocking Government of Haiti Property and Prohibiting Transactions With Haiti," No. 12872 of October 18, 1993, "Blocking Property of Persons Obstructing Democratization in Haiti," No. 12914 of May 7, 1994 "Prohibiting Certain Transactions With Respect to Haiti," No. 12917 of May 21, 1994 "Prohibiting Certain Transactions With Respect to Haiti," No. 12920 of June 10, 1994 "Prohibiting Certain Transactions with Respect to Haiti," and No. 12922 of June 21, 1994 "Blocking Property of Certain Haitian Nationals." The Regulations are being amended to modify sanctions imposed under these orders, although certain prohibitions set forth in the orders themselves are not reflected in the Regulations.

Section 580.211, prohibiting the entry into U.S. ports of vessels engaged in unauthorized trade with Haiti, is removed and reserved. Section 580.518 is added to the Regulations to generally authorize the exportation to Haiti of food and food products. Section 580.519 is added to generally authorize financial transfers to and from Haiti. A conforming amendment is made to § 580.516(a), which authorized certain food exports to Haiti now covered by § 580.518. No payments or transfers to the *de facto* regime in Haiti or to persons listed as Blocked Persons of Haiti in revised appendix A are permitted in connection with transactions authorized pursuant to § 580.518 or § 580.519. Section 580.520 is added to unblock the property of Haitian nationals resident in Haiti not listed in revised appendix A. It does not authorize new transactions with or unblock property of the Government of Haiti or persons listed as Blocked Persons of Haiti in appendix A to part 580.

Section 580.521 is added to inform the public that specific licenses are available on a case-by-case basis for the exportation to Haiti of fuel and equipment for electric power generation, telecommunications materials, media and educational supplies, agricultural supplies and construction and transportation supplies for humanitarian purposes. Section 580.522 is added to announce the availability of specific licenses for certain charter flights for the use of humanitarian organizations and journalists between the United States and Haiti. Such licenses will be issued in conformity with United Nations Security Council procedures with respect to mandatory sanctions against Haiti. Section 580.523 is added to generally license temporary exportation by journalists and broadcast media of equipment to Haiti needed for reporting, broadcasting, and documentary film making there, and for similar temporary importation into the United States of equipment for Haitian journalists and broadcast media.

Finally, appendix A to part 580 ("Blocked Persons of Haiti") is amended to reflect current information on persons whose property remains blocked by provisions contained in Executive Order No. 12775, 12779, 12853, 12872, 12914, 12917, 12920, or 12922. The names of persons whose property was blocked solely on the basis of their status as Haitian nationals resident in Haiti, pursuant to section 1(a) of Executive Order No. 12922, have been removed.

Because the Regulations involve a foreign affairs function, Executive Order 12866 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act, 5 U.S.C. 601-612, does not apply.

List of Subjects in 31 CFR Part 580

Administrative practice and procedure, Agricultural commodities, Banking and finance, Blocking of assets, Exports, Foods, Haiti, Imports.

For the reasons set forth in the preamble, 31 CFR part 580 is amended as set forth below:

PART 580—HAITIAN TRANSACTIONS REGULATIONS

1. The authority citation for part 580 is revised to read as follows:

Authority: 50 U.S.C. 1701-1706; 50 U.S.C. 1601-1651; 22 U.S.C. 287c; 3 U.S.C. 301; E.O. 12775, 56 FR 50641, 3 CFR, 1991 Comp., p. 349; E.O. 12779, 56 FR 55975, 3 CFR, 1991 Comp., p. 367; E.O. 12853, 58 FR 35843, 3 CFR, 1993 Comp., p. 612; E.O. 12872, 58 FR 54029, 3 CFR 1993 Comp., p. 658; E.O. 12914, 59 FR 24339, May 10, 1994; E.O. 12917, 59 FR 26925, May 24, 1994; E.O. 12920, 59 FR 30501, June 14, 1994; E.O. 12922, 59 FR 32645, June 23, 1994.

Subpart B—Prohibitions

§ 580.211 [Removed]

2. Section 580.211 is removed and reserved.

Subpart E—Licenses, Authorizations and Statements of Licensing Policy

3. The heading of § 580.516 is revised to read as follows, and the text is amended by deleting paragraph (a) and

deleting the paragraph designation "(b)" before the remaining text.

§ 580.516 Exportation of propane.

* * * * *

4. Section 580.518 is added to read as follows:

§ 580.518 Exportation of food and food products.

Exportation from the United States to Haiti of food and food products is authorized, provided that no payment or transfer in connection therewith may be made to, from, or through a person listed in appendix A to this part. The authorization contained in this section does not eliminate the need to comply with regulatory requirements governing exports and reexports administered by other federal agencies.

5. Section 580.519 is added to read as follows:

§ 580.519 Financial transfers authorized.

Payments and transfers of funds or other financial or investment assets or credits to Haiti from or through the United States, or to or through the United States from Haiti, otherwise prohibited under section 1 of Executive Order No. 12920, 59 FR 30501 (June 14, 1994), are authorized, provided that no payment or transfer may be made to, from, or through a person listed in appendix A to this part.

6. Section 580.520 is added to read as follows:

§ 580.520 Certain Haitian nationals unblocked.

Except with respect to the property and interests in property of persons listed in appendix A to this part, all property and interests in property of Haitian nationals resident in Haiti otherwise blocked pursuant to section 1(a) of Executive Order No. 12922, 59 FR 32645 (June 23, 1994), are unblocked.

7. Section 580.521 is added to read as follows:

§ 580.521 Licensing of certain exports.

Specific licenses may be issued on a case–by–case basis authorizing the exportation from the United States to Haiti of fuel and equipment for electric power generation, telecommunications materials, media and educational supplies, agricultural supplies, and construction and transportation supplies for humanitarian purposes. No payment or transfer to, from, or through a person listed in appendix A to this part will be authorized in connection with licenses issued under this section.

8. Section 580.522 is added to read as follows:

§ 580.522 Licensing of certain charter flights.

Specific licenses may be issued on a case–by–case basis authorizing charter flights between the United States and Haiti for use by humanitarian relief agencies to transport needed personnel and supplies, or for use by journalists covering events in Haiti. No payment or transfer to, from, or through a person listed in appendix A to this part will be authorized in connection with licenses issued under this section.

8. Section 580.523 is added to read as follows:

§ 580.523 Temporary exports and imports of journalists' and broadcast media equipment.

(a) Journalists and broadcast media may temporarily export from the United States to Haiti equipment needed for reporting and broadcasting from Haiti and for documentary film making in Haiti, provided that such equipment is removed from Haiti as soon as the specific reporting, filming, or broadcasting is completed, and provided that such equipment is not made available for the use of persons listed in appendix A to this part.

(b) Haitian journalists and broadcast media may temporarily import into the United States from Haiti equipment needed for reporting and broadcasting from outside Haiti and for documentary film making outside Haiti.

9. Appendix A to part 580 is revised to read as follows:

APPENDIX A TO PART 580—BLOCKED PERSONS OF HAITI

Note: Section I of appendix A lists the names of individuals whom the Director of the Office of Foreign Assets Control has determined are blocked individuals of Haiti, either because they are included within the definition of the "*de facto* regime in Haiti" as defined in Executive Order 12755, or because they meet criteria for blocking referred to in section 1(b) of Executive Order 12922. Section II of appendix A identifies entities of the *de facto* regime in Haiti whose assets are blocked. Property of these individuals and entities that is located in the United States or within the possession or control of U.S. persons, including their overseas branches, is blocked, and transactions with these individuals and entities are prohibited.

The information listed below is the most complete information now available to the Office of Foreign Assets Control. The absence of any particular person from appendix A is not to be construed as evidence that the person is not a part of, or owned or controlled by, or acting or purporting to act directly or indirectly on behalf of, the *de facto* regime in Haiti, or is not otherwise a blocked individual or entity of Haiti pursuant to the criteria referred to in section 1(b) of Executive Order 12922.

I. Blocked Individuals of Haiti

Name/Rank	Organization	Identifying Information	Date of Birth
ACCLUCHE, Alberic L.; Lieutenant	Haitian Armed Forces	Haiti	29 October 1944
ADOLPHE, François J.; Lieutenant	Haitian Armed Forces	Haiti	7 April 1947
AIMABLE, Jacques Jean; Lieutenant	Haitian Armed Forces	Haiti	21 January 1942
ALCENAT, Jean–Dugas; Lieutenant	Haitian Armed Forces	Haiti	25 June 1940
ALCEUS, Raoul; Captain	Haitian Armed Forces	Haiti	15 April 1953
ALCIDE, Anthony; Major	Haitian Armed Forces	Haiti	15 September 1944
ALCY, Pierre–Antoine; Lieutenant	Haitian Armed Forces	Haiti	15 August 1940
ALEUS, Louisme; Lieutenant	Haitian Armed Forces	Haiti	8 May 1956
ALEXANDRE, Amos; Lieutenant	Haitian Armed Forces	Haiti	24 July 1946
ALEXANDRE, Carel Camille; Lieutenant	Haitian Armed Forces	Haiti	19 July 1963
ALEXANDRE, Dusner; Lieutenant	Haitian Armed Forces	Haiti	27 July 1960
ALEXANDRE, Jean Charlaime; Lieutenant	Haitian Armed Forces	Haiti	1 February 1945
ALEXANDRE, Johel; Lieutenant	Haitian Armed Forces	Haiti	28 March 1954
ALEXANDRE, Joseph Dieunor; Captain	Haitian Armed Forces	Haiti	23 April 1958
ALEXANDRE, Kebeau; Ensign	Haitian Armed Forces	Haiti	30 December 1952
ALEXANDRE, Paul François; Captain	Haitian Armed Forces	Haiti	27 October 1945
ALEXANDRE, Samuel; Captain	Haitian Armed Forces	Haiti	5 October 1955
ALEXIS, Dioget; Lieutenant	Haitian Armed Forces	Haiti	10 July 1959

Name/Rank	Organization	Identifying Information	Date of Birth
ALEXIS, Jean Carlo; Captain	Haitian Armed Forces	haiti	19 January 1958
ALEXIS, Joseph B.; Lieutenant Colonel	Haitian Armed Forces	Haiti	16 January 1942
ALEXIS, Roland; Lieutenant	Haitian Armed Forces	Haiti	22 April 1961
ALFRED, Joseph Brice; Lieutenant	Haitian Armed Forces	Haiti	14 November 1946
ALMONOR, Herard; Lieutenant	Haitian Armed Forces	Haiti	12 August 1948
ALTIDOR, Garie; Captain	Haitian Armed Forces	Haiti	11 April 1958
ALTIDOR, Rodrigue; Lieutenant	Haitian Armed Forces	Haiti	30 November 1950
ALZUPHAR, Aldof; Major	Haitian Armed Forces	Haiti	16 December 1946
ALZUPHAR, Jean-Marie B.; Lieutenant	Haitian Armed Forces	Haiti	21 November 1960
ANDOU, Adolphe; Captain	Haitian Armed Forces	Haiti	24 May 1953
ANDRÉ, Amos; Senator	Haitian Parliament	Haiti	30 March 1957
ANDRÉ, Charles Altenor; Commander	Haitian Armed Forces	Les Cayes, Haiti	1 December 1953
ANDRÉ, Louis-Frito; Lieutenant	Haitian Armed Forces	Haiti	7 June 1948
ANDRÉ, Ruguins; Lieutenant	Haitian Armed Forces	Haiti	1 October 1964
ANDRÉ, Voltaire; Lieutenant	Haitian Armed Forces	Haiti	15 December 1950
ANDRESOL, Mario; Lieutenant	Haitian Armed Forces	Haiti	20 July 1960
ANIS, Venus; Lieutenant	Haitian Armed Forces	Haiti	29 April 1946
ANTOINE, Jean Edouard M.; Lieutenant	Haitian Armed Forces	Haiti	28 April 1940
ANTOINE, Jonas; Lieutenant	Haitian Armed Forces	Haiti	30 November 1942
ANTOINE, Max		Rue 9, Port-au-Prince, Haiti; Passport No. 318-85 (Haiti)	28 December 1954
ANTOINE, Raynald Fritz; Captain	Haitian Armed Forces	Haiti	24 September 1961
ASMATH, Luc Roger; Lieutenant	Haitian Armed Forces	Haiti	4 June 1953
ATOURISTE, Antoine; Colonel	Haitian Armed Forces	Delmas 31, Rue Verly 9, Port-au-Prince, Haiti; Passport No. 79-039396	3 July 1951
ATOURISTE, Antoine, Jr.		Son of Col. Antoine Atouriste; Haiti	12 November 1976
ATOURISTE, Vladimir Ahmed		Son of Col. Antoine Atouriste; Haiti	13 August 1984
AUDATE, Frantz; Lieutenant	Haitian Armed Forces	Haiti	16 June 1968
AUGUSTIN, Anne Mario; Lieutenant	Haitian Armed Forces	Haiti	10 July 1961
AUGUSTIN, Edner; Captain	Haitian Armed Forces	Haiti	19 May 1949
AUGUSTIN, Gabriel		Haiti	1 February 1945
AUGUSTIN, Henry Robert; Colonel	Haitian Armed Forces	Haiti	21 June 1951
AUGUSTIN, Jean-Christophe; Lieutenant	Haitian Armed Forces	Haiti	6 May 1941
AUGUSTIN, Michel; Lieutenant	Haitian Armed Forces	Haiti	4 June 1937
AVRIL, Buteau; Lieutenant	Haitian Armed Forces	Haiti	19 October 1955
BACKER, Jacques (a.k.a. BAKER, Jacques); former Minister	Ministry of Agriculture, National Resources and Rural Development	Lillavois Bon-Repos, Val de Abres 11, Haiti	1 March 1940
BACKER, Marie		Wife of Jacques Backer; Lillavois Bon-Repos, Val de Abres 11, Haiti	25 December 1949
BAGUIDY, Joseph Dominique; former Deputy Chief	Haiti Police	Haiti	20 April 1946
BARTHELEMY, Joseph Luma; Lieutenant	Haitian Armed Forces	Haiti	14 January 1954
BARTHELUS, Joseph; Lieutenant	Haitian Armed Forces	Haiti	28 October 1948
BASTIEN, Baker; Lieutenant Colonel	Haitian Armed Forces	Haiti	31 May 1946
BASTIEN, Karl-Henry; Lieutenant	Haitian Armed Forces	Haiti	13 December 1958
BASTIEN, Ludwig; Lieutenant	Haitian Armed Forces	Haiti	14 June 1963
BASTIEN, Patrick Henri; Captain	Haitian Armed Forces	Haiti	26 April 1958
BAZARD, Louis Eric; Lieutenant	Haitian Armed Forces	Haiti	4 April 1937
BAZELAIS, Antoine; Major	Haitian Armed Forces	Haiti	20 February 1940
BAZILE, David; Major	Haitian Armed Forces	Haiti	4 August 1955
BAZILE, Franck; Lieutenant	Haitian Armed Forces	Haiti	16 December 1958
BAZILE, Serge; Lieutenant	Haitian Armed Forces	Haiti	15 April 1950
BAZIN, Marc L.; former Prime Minister		Haiti	6 March 1932
BEAUBIEN, Fontane; Major	Haitian Armed Forces	Haiti	20 August 1954
BEAUBRUN, Mondesir; Colonel	Haitian Armed Forces	Delmas 75, Port-au-Prince, Haiti	10 May 1949
BEAUBRUN, Noël Sylvatt; Captain	Haitian Armed Forces	Haiti	25 December 1938
BEAUDOUIN, Louis Jacques; Major	Haitian Armed Forces	Haiti	21 July 1948
BEAUGE, Hugo; Lieutenant	Haitian Armed Forces	Haiti	22 May 1961
BELHOMME, Patrick; Lieutenant	Haitian Armed Forces	Haiti	4 May 1959
BELNEAU, Sylvio; Lieutenant	Haitian Armed Forces	Haiti	18 August 1938
BELZIR, Ecclesiaste; Lieutenant	Haitian Armed Forces	Haiti	19 February 1954
BENECHE, Ery; Lieutenant	Haitian Armed Forces	Haiti	19 December 1949
BENJAMIN, Dumas	Central Bank of Haiti	P.O. Box 2450, Port-au-Prince, Haiti	1 September 1949
BENOIT, Etienne; Lieutenant Colonel	Haitian Armed Forces	Haiti	13 January 1935
BENOIT, François; former Minister	Ministry of Foreign Affairs and Worship	Haiti	2 May 1936
BERNARD, Lesly; Lieutenant	Haitian Armed Forces	Haiti	1 April 1968
BERTIN, Mireille Durocher		Legal Counsel to LTG Raoul Cedras; Rue Duncombe 31, Port-au-Prince, Haiti; Passport No. 79-16252	20 October 1959
BERTRAND, Dezile; Major	Haitian Armed Forces	Haiti	31 March 1951
BERTRAND, Dominique; Lieutenant	Haitian Armed Forces	Haiti	14 April 1953

Name/Rank	Organization	Identifying Information	Date of Birth
BIAMBY, Philippe; Brigadier General	Haitian Armed Forces	Haiti	21 September 1952
BIJOUX, Frantz; Lieutenant	Haitian Armed Forces	Haiti	20 May 1962
BISSAINTHE; Gérard		25 Ruye Capoi, Port-au-Prince, Haiti	16 December 1929
BLAISE, Jean-Baptiste P.; Lieutenant	Haitian Armed Forces	Haiti	16 March 1964
BLANC, Andrée G.; Lieutenant	Haitian Armed Forces	Haiti	21 September 1956
BOISNORD, Lherisse; Lieutenant	Haitian Armed Forces	Haiti	3 February 1948
BOISROND, Jean, Dr.; Minister	Ministry of Public Health	Haiti	2 December 1946
BOSQUET, Charlemagne; Lieutenant	Haitian Armed Forces	Haiti	12 January 1948
BOUCARD, Arnoux	Government Industrial Park	Passport No. 86-312687 (Haiti); Haiti	21 January 1935
BOUCARD, Rosevald; Lieutenant	Haitian Armed Forces	Haiti	18 October 1960
BOUCHER, Edner; Major	Haitian Armed Forces	Haiti	24 March 1956
BOULIN, Marie-Carmelle; Captain	Haitian Armed Forces	Haiti	15 July 1955
BOURDEAU, Serge; Lieutenant Colonel	Haitian Armed Forces	Haiti	29 August 1945
BOYER, Christophe D.; Lieutenant	Haitian Armed Forces	Haiti	19 September 1955
BRICE, François; Lieutenant	Haitian Armed Forces	Haiti	15 May 1953
BROSSARD, Harry Alix; Lieutenant	Haitian Armed Forces	Haiti	4 April 1950
BRUNEAU, Jean-Rotchild; Captain	Haitian Armed Forces	Haiti	5 June 1954
BRUTUS, André; former Minister	Ministry of Social Affairs	Rue de Centre No. 134, Port-au-Prince, Haiti	6 August 1943
BRUTUS, Jean Emmanuel; Director	Télénationale d'Haïti	Delmas 60 No. 15, Port-au-Prince, Haiti; Passport No. 83-92060 (Haiti)	20 October 1958
BRUTUS, Patrick		Delmas 40, National Shopping Center c/o Brutus Press Agency, Port-au-Prince, Haiti	6 October 1952
CADET, Ebrane; First Secretary	Executive Bureau of "January 18" Senate	Haiti, possible legal permanent resident of the United States	1 June 1947
CADET, Emmanuel; Captain	Haitian Armed Forces	Haiti	5 February 1946
CALIXTE, Alix Calice; Lieutenant	Haitian Armed Forces	Haiti	25 August 1944
CALIXTE, André; former Minister	Ministry of Information and Coordination	Haiti	13 July 1940
CALIXTE, Geriles; Captain	Haitian Armed Forces	Haiti	4 March 1955
CANTAVE, Jean-Rociny; Lieutenant	Haitian Armed Forces	Haiti	16 May 1938
CARRENARD, Philippe; Colonel	Haitian Armed Forces	Haiti	14 May 1949
CAZEAU, Jean-Lucien; Lieutenant Colonel	Haitian Armed Forces	Haiti	4 January 1951
CEDRAS, Christian		Son of LTG Raoul Cedras; Haiti	17 September 1984
CEDRAS, Didier		Imp. Sambour 126, Port-au-Prince, Haiti	January 1940
CEDRAS, Michaelle		Daughter of LTG Raoul Cedras; Haiti	28 February 1980
CEDRAS, Raoul; Lieutenant General	Haitian Armed Forces	Haiti	9 July 1949
CEDRAS, Raoul Olivier		Son of LTG Raoul Cedras; Haiti	18 August 1977
CEDRAS, Yanick		Wife of LTG Raoul Cedras; Haiti	2 January 1954
CELESTIN, Eddie (a.k.a. CELESTIN, Eddy)	Civil Aviation Authority	Haiti; Passport No. 79-2874 (Haiti)	13 May 1940
CELESTIN, Yves; Lieutenant Commander	Haitian Armed Forces	Haiti	19 October 1954
CELIN, Franck; Lieutenant Colonel	Haitian Armed Forces	Haiti	10 September 1950
CENAFILS, Castera; Captain	Haitian Armed Forces	Haiti	22 October 1953
CENEAC, Rony; Lieutenant	Haitian Armed Forces	Haiti	18 January 1960
CESAR, Abelar; Lieutenant	Haitian Armed Forces	Haiti	8 January 1956
CESAR, Jean-Kermichel; Lieutenant	Haitian Armed Forces	Haiti	9 September 1943
CETOUTE, Julis; Lieutenant	Haitian Armed Forces	Haiti	4 March 1951
CHAM, Julio, Lieutenant	Haitian Armed Forces	Haiti	5 November 1947
CHAMBLAIN, Louis Judel	Revolutionary Front for Advancement and Progress of Haiti (FRAPH)	Haiti	
CHAMPAGNE, Jean Yves Hancy; Captain	Haitian Armed Forces	Haiti	6 February 1960
CHAMPAGNE, Leisner, Lieutenant	Haitian Armed Forces	Haiti	14 July 1959
CHAPUSETTE, Marie Carline; Lieutenant	Haitian Armed Forces	Haiti	24 January 1960
CHARLES, Alexis Volcy L.; Ensign	Haitian Armed Forces	Haiti	22 March 1966
CHARLES, Astrel; Lieutenant	Haitian Armed Forces	Haiti	25 December 1950
CHARLES, Benoit; Lieutenant	Haitian Armed Forces	Haiti	12 May 1959
CHARLES, Faustin; Lieutenant	Haitian Armed Forces	Haiti	20 August 1951
CHARLES, Jean Clement; Lieutenant	Haitian Armed Forces	Haiti	8 September 1948
CHARLES, Josel; Major	Haitian Armed Forces	Haiti	23 February 1951
CHARLES, Joseph; Lieutenant	Haitian Armed Forces	Haiti	6 March 1938
CHARLES, Martin Laerte; Lieutenant	Haitian Armed Forces	Haiti	27 July 1957
CHARLES, Mercidieu; Lieutenant	Haitian Armed Forces	Haiti	5 August 1953
CHARLES, Pierre Gerald; Captain	Haitian Armed Forces	Haiti	9 July 1959
CHARLES, Pierre-Hemeric; Captain	Haitian Armed Forces	Haiti	6 July 1957
CHARLES, Soifaite; Lieutenant	Haitian Armed Forces	Haiti	21 December 1936
CHARLES, Webert; Lieutenant	Haitian Armed Forces	Haiti	15 April 1957
CHARLES-PIERRE, Jean-Marie; Lieutenant	Haitian Armed Forces	Haiti	8 August 1959
CHARLES-PIERRE, Lima J.; Captain	Haitian Armed Forces	Haiti	2 December 1955

Name/Rank	Organization	Identifying Information	Date of Birth
CHARLES–PIERRE, Sandry F.M.; Captain	Haitian Armed Forces	Haiti	2 June 1961
CHARLEUS, Joseph Rivaud; Lieutenant	Haitian Armed Forces	Haiti	18 January 1940
CHARLIER, Antony; Captain	Haitian Armed Forces	Haiti	27 October 1958
CHARLOTIN, Fritz; Lieutenant	Haitian Armed Forces	Haiti	15 December 1953
CHATELIN, Lucien A.; Captain	Haitian Armed Forces	Haiti	6 June 1941
CHERENEFANT, Tony; Lieutenant	Haitian Armed Forces	Haiti	8 August 1937
CHERFILS, Serge; Lieutenant	Haitian Armed Forces	Haiti	10 March 1947
CHERISKA, Eric; Lieutenant	Haitian Armed Forces	Haiti	16 September 1962
CHERY, Fritzner; Lieutenant	Haitian Armed Forces	Haiti	11 October 1960
CHERY, Georges Fils; Lieutenant	Haitian Armed Forces	Haiti	30 May 1951
CHERY, Pierre–André; Lieutenant	Haitian Armed Forces	Haiti	9 July 1959
CHERY, Victor Louis; Captain	Haitian Armed Forces	Haiti	24 December 1938
CINEAS, Alex (a.k.a. CINEAS, Alix)		Delmas 31, Rue Coutard No. 7, Port–au–Prince, Haiti	15 June 1932
CINEAS, Charles R.E.; Major	Haitian Armed Forces	Haiti	24 May 1951
CINEAS, Victor; Lieutenant Colonel	Haitian Armed Forces	Haiti	14 October 1942
CINEUS, Auguste Ulrick; Lieutenant	Haitian Armed Forces	Haiti	21 February 1962
CINTELLUS, Antoine A.H.; Lieutenant	Haitian Armed Forces	Haiti	14 October 1959
CLEMENT, Antony; Captain	Haitian Armed Forces	Haiti	7 May 1954
CLEMENT, Jacques; Lieutenant	Haitian Armed Forces	Haiti	27 January 1959
CLERJEUNE, Adeline		Wife of Col. Leopold Clerjeune; Haiti	27 Jun 50
CLERJEUNE, Christian		Son of Col. Leopold Clerjeune; Haiti	7 Dec 82
CLERJEUNE, Leopold; Colonel	Haitian Armed Forces	Delmas 31, Rue E. Laforest, Port–au–Prince, Haiti; Passport No. 90678797	24 August 1950
CLERJEUNE, Sethi		Son of Col. Leopold Clerjeune; Haiti	25 Feb 81
CLERMONT, Jean–Roger; Captain	Haitian Armed Forces	Haiti	24 October 1938
COFFY, Gesner; Lieutenant	Haitian Armed Forces	Haiti	20 August 1955
CONSTANT, Emmanuel "Toto"		Haiti	27 December 1956
CORENTIN, Willio; Lieutenant	Haitian Armed Forces	Haiti	20 February 1953
CORIDON, Clausel; Lieutenant	Haitian Armed Forces	Haiti	29 September 1959
CORVIL, Saint–Jean; Lieutenant	Haitian Armed Forces	Haiti	8 February 1948
COUTARD, Marie E.C.; Captain	Haitian Armed Forces	Haiti	19 November 1954
CREVECOEUR, Rodrigue; Lieutenant Colonel	Haitian Armed Forces	Haiti	10 February 1955
CYPRIEN, Jean Thomas; Lieutenant Colonel	Haitian Armed Forces	Haiti	24 April 1958
CYRILLE, Denis; Lieutenant Colonel	Haitian Armed Forces	Haiti	18 November 1944
DAGRIN, Pleno; Lieutenant	Haitian Armed Forces	Haiti	12 August 1946
DAVID, Charles; Minister	Ministry of Foreign Affairs and Worship	Haiti	27 March 1941
DE RONCERAY, Hubert	Mobilization for National Development	Haiti	20 August 1932
DEBROSSE, Neptune M.; Captain	Haitian Armed Forces	Haiti	21 May 1944
DEEB, Joel		Haiti; U.S.A	28 June 1954
DEGRAFF, Claude Bernard (a.k.a. Bernard DESGRAFF); Director	Télénationale D'Haïti	Route Peguyville No. 1, Port–au–Prince, Haiti; Passport No. 79–015305 (Haiti)	9 July 1959
DEGRAFF, Jean Ernst; Lieutenant	Haitian Armed Forces	Haiti	24 November 1943
DELAUNAY, Joseph Gracien; Colonel	Haitian Armed Forces	Haiti	21 January 1949
DELILE, Jehova; Lieutenant	Haitian Armed Forces	Haiti	14 July 1948
DELSOIN, Jean Robert; Minister	Ministry of Commerce and Industry	Port–au–Prince, Haiti	2 May 1944
DELTOR, Pierre Camil; Lieutenant	Haitian Armed Forces	Haiti	6 February 1961
DELVA, Reginald; Lieutenant	Haitian Armed Forces	Haiti	31 August 1967
DENIS, Carl		No. 38, Rue Chavannes, Port–au–Prince, Haiti	20 April 1943
DENIS, Jacques; Major	Haitian Armed Forces	Haiti	9 March 1955
DERVIL, Elie–Franc; Lieutenant	Haitian Armed Forces	Haiti	10 September 1955
DERVILUS, André Labanet; Lieutenant	Haitian Armed Forces	Haiti	28 December 1940
DESAMOURS, Antoinius; Lieutenant	Haitian Armed Forces	Haiti	16 October 1948
DESARMES, Louis; Lieutenant	Haitian Armed Forces	Haiti	2 May 1938
DESGRAFF, Bernard (a.k.a. Claude Bernard DEGRAFF); Director	Télénationale D'Haïti	Route Peguyville No. 1, Port–au–Prince, Haiti; Passport No. 79–015305 (Haiti)	9 July 1959
DESIR, Joseph; former Minister	National Education	Haiti	18 Feb 48
DESIR, Roland; Captain	Haitian Armed Forces	Haiti	24 November 1955
DESPLANTES, Serge; Major	Haitian Armed Forces	Haiti	18 February 1955
DESROSE, Jean–Philippe; Lieutenant	Haitian Armed Forces	Haiti	7 January 1949
DESROSIERS, Eddy; Lieutenant	Haitian Armed Forces	Haiti	3 November 1961
DESROSIERS, Jean–Guy; Lieutenant	Haitian Armed Forces	Haiti	4 March 1946
DESROSIERS, Joseph Hubert; Lieutenant	Haitian Armed Forces	Haiti	12 November 1940
DESSANT, Joseph Franck; Lieutenant	Haitian Armed Forces	Haiti	7 June 1955
DESSIN, Jean Baptiste C.; Captain	Haitian Armed Forces	Haiti	15 January 1944
DEUS, Damas; Lieutenant	Haitian Armed Forces	Haiti	1 August 1939
DEVILMA, Joseph M.; Lieutenant Colonel	Haitian Armed Forces	Haiti	4 December 1948
DIEUDONNE, Brutus M.; Colonel	Haitian Armed Forces	Haiti	3 December 1938

Name/Rank	Organization	Identifying Information	Date of Birth
DIEUDONNE, Louicin; Lieutenant	Haitian Armed Forces	Haiti	25 September 1961
DIMANCHE, Jean-Robert; Lieutenant	Haitian Armed Forces	Haiti	4 August 1945
DOLCINE, Jean-Marty; Captain	Haitian Armed Forces	Haiti	26 October 1939
DOMINIQUE, Jean Claude; Lieutenant	Haitian Armed Forces	Haiti	2 September 1951
DOMINIQUE, Ralph; Lieutenant	Haitian Armed Forces	Haiti	11 February 1961
DORCÉ, Saintalus; Lieutenant	Haitian Armed Forces	Haiti	26 July 1953
DORELIEN, Carl; Colonel	Haitian Armed Forces	Haiti; Passport No. 82-57899	24 January 1949
DORELIEN, Didier Davis		Son of Col. Carl Dorelien; Haiti	4 December 1981
DORELIEN, Giovanni Emmanuel		Son of Col. Carl Dorelien; Haiti	23 December 1980
DORELIEN, Karl Steven		Son of Col. Carl Dorelien; Haiti	14 July 1979
DORELIEN, Marie Carline		Wife of Col. Carl Dorelien; Haiti	12 December 1953
DORGELUS, Ludovic; Lieutenant	Haitian Armed Forces	Haiti	7 September 1940
DORVAL, Ilertant; Lieutenant	Haitian Armed Forces	Haiti	4 July 1943
DORVAL, Paul; Major	Haitian Armed Forces	Haiti	8 November 1949
DORVELUS, Lionel; Lieutenant	Haitian Armed Forces	Haiti	10 August 1945
DORVIL, Roland; Lieutenant	Haitian Armed Forces	Haiti	20 October 1953
DORVILIER, Jean Christian; Lieutenant	Haitian Armed Forces	Haiti	9 September 1939
DORZIN, Abner; Ensign	Haitian Armed Forces	Haiti	7 August 1950
DOUBY, Camille		Wife of Colonel Frantz Douby; Rue Cheriez 9, Rue 4 No. 8, Port-au-Prince, Haiti	18 July 1955
DOUBY, Frantz; Colonel	Haitian Armed Forces	Rue Cheriez 9, Rue 4 No. 8, Port-au-Prince, Haiti	19 January 1948
DOUILLON, Lamartine; Lieutenant Colonel	Haitian Armed Forces	Haiti	22 July 1948
DOURA, Stagne; Captain	Haitian Armed Forces	Haiti	18 January 1958
DUBIC, Joseph Raoul; Lieutenant	Haitian Armed Forces	Haiti	8 February 1941
DUBUCHE, Berrier; Captain	Haitian Armed Forces	Haiti	18 May 1945
DUCHEMIN, Guy; Colonel	Haitian Armed Forces	Haiti	29 September 1931
DUFRESNE, Jean Roland; Major	Haitian Armed Forces	Haiti	11 June 1956
DUMAS, Joseph Laurent; Major	Haitian Armed Forces	Haiti	9 July 1947
DUMERGEANT, Gilius J.; Captain	Haitian Armed Forces	Haiti	17 January 1941
DUMORIN, Ls. Maoari; Lieutenant	Haitian Armed Forces	Haiti	25 January 1948
DUMORNAY, Joseph Justin; Lieutenant	Haitian Armed Forces	Haiti	31 March 1968
DUPERVAL, Ana Siobhan		Daughter of Maj. Gen. Jean Claude Duperval; Haiti	27 May 1988
DUPERVAL, Jean-Claude; Major General	Haitian Armed Forces	Haiti	19 February 1947
DUPLAN, Rigaud; Minister	Ministry of Economy and Finance	Haiti	1 August 1941
DUPOUX, Serge; Major	Haitian Armed Forces	Haiti	22 January 1956
DUTREUIL, Jean-Marie; Deputy Director	Office for Permanent Maintenance of Road Network	Boite Vertallis No. 1, Port-au-Prince, Haiti; Passport No. 80-70804 (Haiti)	30 May 1950
DUVERNE, Jean Emmanuel; Major	Haitian Armed Forces	Haiti	22 November 1951
DUVERSEAU, Jean-Robert; Lieutenant	Haitian Armed Forces	Haiti	27 May 1954
EDOUARD, Charles; Lieutenant	Haitian Armed Forces	Haiti	12 January 1946
EDOUARD, Eddy; Lieutenant	Haitian Armed Forces	Haiti	19 November 1962
EDOUARZIN, Jean Maurice; Captain	Haitian Armed Forces	Haiti	25 October 1944
ELIE, Jean-Nesly; Lieutenant	Haitian Armed Forces	Haiti	2 December 1960
ELIE, Ralph; Director	Conseil National des Télécommunications	Kilometer 11, Bon Repos, Haiti; Passport No. 82-46261 (Haiti)	31 August 1952
ELYSEE, Antoine Fenelon; Lieutenant	Haitian Armed Forces	Haiti	13 June 1936
ELYZEE, Yonel "SonSon"		Route Jacquet No. 15, Delmas 95, Port-au-Prince, Haiti; Passport No. 92-011253 (Haiti)	19 July 1951
EMILE, Jean Abner; Captain	Haitian Armed Forces	Haiti	29 January 1956
EMILE, Saint-Louis; Lieutenant	Haitian Armed Forces	Haiti	1 July 1940
EMILIEN, Michel; Lieutenant	Haitian Armed Forces	Haiti	12 June 1939
EMMANUEL, Exaus; Lieutenant	Haitian Armed Forces	Haiti	5 January 1940
ESTIMABLE, Sedeine; Lieutenant	Haitian Armed Forces	Haiti	7 March 1949
ESTIME, Alexandre; Lieutenant	Haitian Armed Forces	Haiti	11 September 1953
ETIENNE, Ariste Harry; Lieutenant	Haitian Armed Forces	Haiti	27 October 1958
ETIENNE, Jean-Mary; Major	Haitian Armed Forces	Haiti	21 September 1952
ETIENNE, Joasilien; Lieutenant	Haitian Armed Forces	Haiti	10 July 1954
ETIENNE, Lord Warner; Major	Haitian Armed Forces	Haiti	22 March 1952
ETIENNE, Renan; Lieutenant	Haitian Armed Forces	Haiti	17 August 1964
EUGENE, Antoine; Lieutenant	Haitian Armed Forces	Haiti	21 July 1942
EUSTACHE, Wilson; Colonel	Haitian Armed Forces	Haiti	20 November 1942
EXCELLENT, Bertrand Ronald; Lieutenant	Haitian Armed Forces	Haiti	24 May 1961
EXCEUS, Rock; Lieutenant	Haitian Armed Forces	Haiti	16 August 1961
FAIETON, Dieudonne; Lieutenant	Haitian Armed Forces	Haiti	31 December 1953
FELIX, Jean-Daniel; Lieutenant	Haitian Armed Forces	Haiti	13 May 1959
FELIX, Jean-Rabel; Lieutenant	Haitian Armed Forces	Haiti	15 February 1957
FETIERE, Edmond; Captain	Haitian Armed Forces	Haiti	9 March 1962
FIDELE, Jean-Luckner; Lieutenant	Haitian Armed Forces	Haiti	5 August 1960

Name/Rank	Organization	Identifying Information	Date of Birth
FILS–AIMÉ, Gérard; Lieutenant	Haitian Armed Forces	Haiti	2 October 1944
FILS–AIMÉ, Hervé; Lieutenant	Haitian Armed Forces	Haiti	10 January 1963
FILTIDOR, Louis Jean; Lieutenant	Haitian Armed Forces	Haiti	27 February 1946
FLEURY, Antoine; Lieutenant	Haitian Armed Forces	Haiti	27 July 1963
FLOREAL, Marc; Lieutenant	Haitian Armed Forces	Haiti	25 April 1942
FLORESTANT, Joseph Lemoine; Colonel	Haitian Armed Forces	Haiti	18 November 1949
FLOREXIL, Edwin; Major	Haitian Armed Forces	Haiti	4 February 1955
FLORIVAL, Jean; Deputy Director	Ministry of Foreign Affairs and Worship	Haiti	1 February 1930
FORCANT, Carol; Captain	Haitian Armed Forces	Haiti	26 January 1939
FORD, Emmanuel; Minister	Ministry of Planning and External Cooperation	Haiti	13 May 1933
FORT, Wiener (a.k.a. FORT, Weiner)	Ministry of Economy and Finance	Haiti	15 October 1941
FOUCAND, Hervé (a.k.a. FOURCAND, Hervé)		Rue Marcadie, Bourdon, Port–au–Prince, Haiti	14 June 1964
FRANCE, Pierre–Noël; Lieutenant	Haitian Armed Forces	Haiti	18 December 1952
FRANÇOIS, Evans Macfarland		Haiti; Dominican Republic; Passport No. 466–91; Diplomatic Passport No. 92–012658	6 May 1952
FRANÇOIS, Guy; former Deputy Minister	Ministry of Interior and National Defense	Haiti	04 April 1953
FRANÇOIS, Jean Hervay; Lieutenant	Haitian Armed Forces	Haiti	9 November 1947
FRANÇOIS, Jean–Pierre; Major	Haitian Armed Forces	Haiti	18 March 1951
FRANÇOIS, Jerome; Lieutenant	Haitian Armed Forces	Haiti	4 April 1944
FRANÇOIS, Joseph Michel; Lieutenant Colonel	Haitian Armed Forces	Route Aeroport, Rue Bergera, Imp. Beauchamp No. 2, Port–au–Prince, Haiti; Passport No. 81151112	8 May 1957
FRANÇOIS, Paul Audmar; Lieutenant	Haitian Armed Forces	Haiti	20 August 1962
GABRIEL, Jean Robert; Colonel	Haitian Armed Forces	Haiti	11 August 1953 or 1958
GABRIEL, Yolette Cantave		Route Car. 3è Mais. Après Tribunal, Port–au–Prince, Haiti	1 June 1954
GARCON, Alterme Maurice; Lieutenant	Haitian Armed Forces	Haiti	26 July 1945
GARCON, Denoit Ceracius; Lieutenant	Haitian Armed Forces	Haiti	22 Oct 53
GASSAN, Jean Necker; Lieutenant Colonel	Haitian Armed Forces	Haiti	12 February 1942
GAUBERT, Carlyle; Lieutenant	Haitian Armed Forces	Haiti	9 March 1959
GAY, Pierre Gerald; Ensign	Haitian Armed Forces	Haiti	23 December 1963
GEDEON, Jean Evans; Lieutenant–Colonel	Haitian Armed Forces	Haiti	11 April 1944
GEORGEON, Joseph Horres; Lieutenant	Haitian Armed Forces	Haiti	14 January 1951
GEORGES, François Arnold; Lieutenant	Haitian Armed Forces	Haiti	4 September 1942
GEORGES, Reynald		Haiti; U.S.A	16 October 1946
GERMAIN, Anglade; Lieutenant	Haitian Armed Forces	Haiti	13 July 1939
GERMAIN, Destorel; Lieutenant	Haitian Armed Forces	Haiti	4 September 1951
GERMAIN, Henri P.; Lieutenant–Colonel	Haitian Armed Forces	Haiti	6 September 1951
GERMAIN, Petiel; Lieutenant	Haitian Armed Forces	Haiti	9 January 1938
GILLES, Joseph Harry; Lieutenant	Haitian Armed Forces	Haiti	22 January 1962
GIRAUD, Michel P. L.; Captain	Haitian Armed Forces	Haiti	14 December 1940
GOBY, Jean Brunel; Colonel	Haitian Armed Forces	Haiti	28 September 1951
GONEL, Bertrand; Lieutenant	Haitian Armed Forces	Haiti	10 April 1961
GRACIA, Diderot; Captain	Haitian Armed Forces	Haiti	13 March 1954
GREFFIN, Jean Gary; Captain	Haitian Armed Forces	Haiti	6 December 1958
GROSHOMME, Belony; Colonel	Haitian Armed Forces	Haiti; Passport No. 81–161845	12 February 1948
GUERRIER, Derby; Lieutenant–Colonel	Haitian Armed Forces	Drouillard Sarthe Village, Port–au–Prince, Haiti; Passport No. 85–271932	14 October 1949
GUERRIER, Jean Roger; Major	Haitian Armed Forces	Haiti	20 April 1957
GUILLAUME, Edouard Saint–Jean; Member	Chamber of Deputies of Haitian Parliament	Haiti	19 February 1936
GUILLAUME, Flobert; Lieutenant	Haitian Armed Forces	Haiti	28 June 1961
GUILLAUME, Luc–Claudin; Lieutenant	Haitian Armed Forces	Haiti	30 September 1944
GUILLAUME–SAM, Jusmide; Lieutenant	Haitian Armed Forces	Haiti	24 July 1952
GUILLAUMETTE, Antoine; Lieutenant	Haitian Armed Forces	Haiti	8 November 1951
GUSTAVE, Christian; Lieutenant	Haitian Armed Forces	Haiti	3 February 1943
GUSTAVE, Joaname; Lieutenant	Haitian Armed Forces	Haiti	10 October 1952
HAGE, Mona Isable; Captain	Haitian Armed Forces	Haiti	29 May 1952
HALLOUN, Romeo		U.S. citizen; Passport No. Z5790133	18 January 1957
HENRY, Jean–Mary Fritz; Major	Haitian Armed Forces	Haiti	8 June 1951
HENRY, Vemarie; Lieutenant	Haitian Armed Forces	Haiti	10 April 1955
HENRYS, Antoine Gracia; Lieutenant	Haitian Armed Forces	Haiti	20 January 1944
HERMANN, Michel–Ange; Lieutenant Colonel	Haitian Armed Forces	Haiti	3 October 1952
HEROLD, André; Lieutenant	Haitian Armed Forces	Haiti	23 March 1959
HILAIRE, Max; Captain	Haitian Armed Forces	Haiti	3 July 1960
HILMAIN, Adrien D.; Lieutenant	Haitian Armed Forces	Haiti	7 February 1945

Name/Rank	Organization	Identifying Information	Date of Birth
HONORAT, Jean-Jacques	Ministry of Foreign Affairs and Worship	Haiti	1 April 1931
IRA, Joseph Miracle; Major	Haitian Armed Forces	Haiti	14 March 1951
JACOB, Joseph Pierre; Colonel	Haitian Armed Forces	Haiti	22 April 1940
JACOT, Eristhene; Captain	Haitian Armed Forces	Haiti	22 June 1951
JACQUES, Antoine; Lieutenant	Haitian Armed Forces	Haiti	24 November 1950
JACQUES, Georges I.; Lieutenant	Haitian Armed Forces	Haiti	28 December 1940
JACQUES, Herard-Leblanc; Lieutenant	Haitian Armed Forces	Haiti	16 October 1944
JACQUES, Joseph Yvon; Lieutenant	Haitian Armed Forces	Haiti	8 March 1947
JACQUES, Josue; Lieutenant	Haitian Armed Forces	Haiti	17 April 1945
JACQUES-LOUIS, Max; Lieutenant	Haitian Armed Forces	Haiti	4 June 1964
JACQUET, Henrius; Captain	Haitian Armed Forces	Haiti	18 September 1951
JACQUITTE, Jean Wener; Lieutenant	Haitian Armed Forces	Haiti	17 March 1967
JANVIER, Jean-Jacques; Lieutenant	Haitian Armed Forces	Haiti	18 March 1935
JASMIN, Jacques-Guy; Lieutenant	Haitian Armed Forces	Haiti	22 November 1945
JEAN, Gracia	Ministry of Interior and National Defense	Haiti	4 October 1937
JEAN, Hasler A.; Lieutenant	Haitian Armed Forces	Haiti	15 October 1950
JEAN, Jonas; Colonel	Haitian Armed Forces	Haiti	12 September 1951
JEAN, Kenol		Haiti	1 July 1961
JEAN, Phito; Captain	Haitian Armed Forces	Haiti	2 April 1954
JEAN, Rigaud; Lieutenant	Haitian Armed Forces	Haiti	19 November 1942
JEAN-BAPTISTE, Charles Eusebe; Colonel	Haitian Armed Forces	Haiti	19 July 1942
JEAN-BAPTISTE, Elysee; Lieutenant	Haitian Armed Forces	Haiti	17 September 1946
JEAN-BAPTISTE, James; Captain	Haitian Armed Forces	Haiti	30 July 1959
JEAN-BAPTISTE, Jean Occelus; Lieutenant	Haitian Armed Forces	Haiti	16 April 1944
JEAN-BAPTISTE, Lyonel; Captain	Haitian Armed Forces	Haiti	1 March 1947
JEAN-BAPTISTE, Michel-Ange; Lieutenant	Haitian Armed Forces	Haiti	5 June 1960
JEAN-BAPTISTE, Pierre-Jacques; Lieutenant	Haitian Armed Forces	Haiti	12 September 1955
JEAN-BAPTISTE, Rodiny; Captain	Haitian Armed Forces	Haiti	5 October 1959
JEAN-BART, Thomas Kerns; Captain	Haitian Armed Forces	Haiti	7 March 1959
JEAN-BRICE, Ralph Stanley; Lieutenant	Haitian Armed Forces	Haiti	25 March 1968
JEAN-CHARLES, Frantz S.; Captain	Haitian Armed Forces	Haiti	17 December 1960
JEAN-FRANÇOIS, Frantz; Lieutenant	Haitian Armed Forces	Haiti	23 June 1960
JEAN-FRANÇOIS, Serge; Lieutenant	Haitian Armed Forces	Haiti	15 February 1950
JEAN-GILLES, André M.; Colonel	Haitian Armed Forces	Haiti	19 April 1931
JEAN-JACQUES, Yvon; Captain	Haitian Armed Forces	Haiti	25 November 1958
JEAN-PAUL, Innocent J.-C; Lieutenant	Haitian Armed Forces	Haiti	24 April 1949
JEAN-PHILIPPE, Joseph Nevert; Lieutenant	Haitian Armed Forces	Haiti	3 October 1950
JEAN-PIERRE, Arinks; Member	Chamber of Deputies of Haitian Parliament	Haiti	15 September 1947
JEAN-PIERRE, Gannel; Lieutenant	Haitian Armed Forces	Haiti	13 May 1961
JEAN-PIERRE, Mignard; Lieutenant	Haitian Armed Forces	Haiti	13 October 1968
JEAN-PIERRE, Saint Surin; Lieutenant	Haitian Armed Forces	Haiti	16 January 1941
JEANNITE, Alfred; Lieutenant	Haitian Armed Forces	Haiti	11 July 1946
JEANTY, Vladimir		Pontamara 27, No. 51, Port-au-Prince, Haiti	15 January 1948
JEROME, Auguste Raphael; Major	Haitian Armed Forces	Haiti	8 September 1949
JEUDY, Jean-Claude; Lieutenant Colonel	Haitian Armed Forces	Haiti	28 March 1944
JEVOUSAIME, Max; Lieutenant	Haitian Armed Forces	Haiti	26 May 1946
JOACHIM, Marie Gina; Lieutenant	Haitian Armed Forces	Haiti	30 September 1960
JOANIS, Jackson; Captain	Haitian Armed Forces	Ruelle Alix Roy, Imp. Telemaque No. 22, Port-au-Prince, Haiti	25 October 1958
JOANIS, Rachmany		Daughter of Capt. Jackson Joanis; Haiti	15 February, 1986
JOAZILE, Jean-Rodolphe; Lieutenant	Haitian Armed Forces	Haiti	15 September 1962
JOCELYN, Fritz; Colonel	Haitian Armed Forces	Haiti	12 November 1941
JOLICOEUR, Olius; Lieutenant	Haitian Armed Forces	Haiti	18 March 1949
JONASSAINT, Émile, Illegal President		Haiti	20 May 1913
JONASSAINT, Renold; Lieutenant	Haitian Armed Forces	Haiti	6 February 1953
JONQUIS, Antoine; Lieutenant	Haitian Armed Forces	Haiti	19 June 1946
JOSAPHAT, André Claudel; Lieutenant Colonel	Haitian Armed Forces	Haiti	17 August 1956
JOSÉ, Jean-Eugene; Colonel	Haitian Armed Forces	Haiti	10 June 1952
JOSEPH, Antoine Th.; Lieutenant	Haitian Armed Forces	Haiti	2 July 1945
JOSEPH, Claude; Captain	Haitian Armed Forces	Haiti	12 August 1956
JOSEPH, Claudy; Lieutenant	Haitian Armed Forces	Haiti	14 September 1961
JOSEPH, Demes G.; Lieutenant	Haitian Armed Forces	Haiti	4 April 1943
JOSEPH, Frantz; Director	Office for Permanent Maintenance of Road Network	Rue Nazon No. 21, Port-au-Prince, Haiti; Passport No. 80-58147 (Haiti)	13 October 1954
JOSEPH, Jean Beil; Lieutenant	Haitian Armed Forces	Haiti	4 Dec 57
JOSEPH, Jean Ronel; Captain	Haitian Armed Forces	Haiti	15 March 1954
JOSEPH, Jean Ulrique; Lieutenant	Haitian Armed Forces	Haiti	23 September 1937

Name/Rank	Organization	Identifying Information	Date of Birth
JOSEPH, Jethro; Lieutenant	Haitian Armed Forces	Haiti	17 April 1946
JOSEPH, Louisiane; Lieutenant	Haitian Armed Forces	Haiti	26 May 1956
JOSEPH, Milarion Odamus; Lieutenant	Haitian Armed Forces	Haiti	29 April 1941
JOSEPH, Raphael Attilio; Lieutenant	Haitian Armed Forces	Haiti	20 May 1948
JOSEPH, Ricot; Major	Haitian Armed Forces	Haiti	30 October 1950
JOSEPH, St-Fort; Lieutenant	Haitian Armed Forces	Haiti	3 August 1943
JULES, Jean Ader; Lieutenant	Haitian Armed Forces	Haiti	15 October 1961
JULISSE, Rosemond; Lieutenant	Haitian Armed Forces	Haiti	7 March 1952
JUSTAFORT, Coulange; Lieutenant Colonel	Haitian Armed Forces	Haiti	18 April 1950
JUSTAFORT, Serge; Major	Haitian Armed Forces	Haiti	12 June 1955
KERCY, Garry Michel; Captain	Haitian Armed Forces	Haiti	21 September 1960
KERNIZAN, Jean Marc		Son of Maj. Marc Kernizan; Haiti	1 July 1989
KERNIZAN, Marc; Major	Haitian Armed Forces	Delmas 45, No. 8, Port-au-Prince, Haiti	5 September 1955
KERNIZAN, Marie Claire		Wife of Maj. Marc Kernizan; Haiti	9 October 1962
KERNIZAN, Melissa		Daughter of Maj. Marc Kernizan; Haiti	9 September 1986
KERSAINT, Esnaider; Major	Haitian Armed Forces	Haiti	2 January 1953
KHAWLY, Gerald		Boutilier No. 8, Petionville, Haiti	24 February 1940
KHAWLY, Michel Jacques		No. 80 Avenue Baranquilla, Jacmel, Haiti	18 July 1937
LAFOND, Jean-Dorcin; Lieutenant	Haitian Armed Forces	Haiti	15 June 1945
LAMANDE, René Raymond; Lieutenant	Haitian Armed Forces	Haiti	20 May 1942
LAMOUR, Phalange; Lieutenant	Haitian Armed Forces	Haiti	18 November 1946
LAROCHELLE, Gerald; Captain	Haitian Armed Forces	Haiti	4 April 1958
LAROQUE, Serge; Lieutenant	Haitian Armed Forces	Haiti	17 December 1943
LASSEGUE, Pierre Philippe	National Port Authority of Haiti	Haiti; U.S.A; port captain	
LATORTUE, Youri; Lieutenant	Haitian Armed Forces	Haiti	13 November 1967
LAURORE, Appolos; Colonel	Haitian Armed Forces	Haiti	11 March 1954
LAZARRE, Schubert; Lieutenant	Haitian Armed Forces	Haiti	18 February 1950
LEANDRE, Edrick; Captain	Haitian Armed Forces	Haiti	29 September 1952
LEMITHE, Felix; Lieutenant Colonel	Haitian Armed Forces	Haiti	30 April 1943
LENESCAT, Joseph Charlot; Lieutenant	Haitian Armed Forces	Haiti	10 June 1949
LEONARD, Franck; Senator	Haitian Parliament	Haiti	6 November 1925
LEONIDAS, Bernardo R.; Lieutenant-Colonel	Haitian Armed Forces	Rue Oscar No. 23, Port-au-Prince, Haiti	28 February 1942
LESSAGE, Jodel; Colonel	Haitian Armed Forces	Haiti	19 February 1954
LEVASSEUR, Iliovert; Lieutenant	Haitian Armed Forces	Haiti	31 December 1954
LOISEAU, Jenny		Daughter of Maj. Joel Loiseau; Haiti	17 December 1983
LOISEAU, Joel; Major	Haitian Armed Forces	Haiti	11 November 1954
LOISEAU, Ketly		Wife of Maj. Joel Loiseau; Haiti	19 April 1961
LOUIS, Cassinir; Major	Haitian Armed Forces	Haiti	26 July 1952
LOUIS, Dieuphene; Lieutenant	Haitian Armed Forces	Haiti	1 February 1957
LOUIS, Edy; Colonel	Haitian Armed Forces	Haiti	21 June 1951
LOUIS, Gérard E., Jr.; Lieutenant	Haitian Armed Forces	Haiti	5 December 1964
LOUIS, Jean Sagesse; Lieutenant	Haitian Armed Forces	Haiti	27 August 1946
LOUIS, Marc Albert; Major	Haitian Armed Forces	Haiti	26 May 1952
LOUIS, Max-Gabriel; Lieutenant	Haitian Armed Forces	Haiti	6 March 1964
LOUIS, Michel; Colonel	Haitian Armed Forces	Haiti	28 September 1949
LOUIS-JACQUES, Richelet S.; Major	Haitian Armed Forces	Haiti	16 November 1950
LOUISY, Franck; Lieutenant	Haitian Armed Forces	Haiti	7 April 1951
LUBIN, Emmanuel; Lieutenant	Haitian Armed Forces	Haiti	25 December 1944
LUBIN, Ernst J. M.; Major	Haitian Armed Forces	Haiti	1 January 1955
LUMAS, Jean Justin; Lieutenant	Haitian Armed Forces	Haiti	29 September 1943
MAHAUTIERE, Pierre Charles; Lieutenant	Haitian Armed Forces	Haiti	31 August 1944
MARC-CHARLES, Henry (Henri) Robert; Colonel	Haitian Armed Forces	Haiti	5 January 1952
MARC-CHARLES, Monique (Marie Florence)		Wife of Col. Henry Robert Marc-Charles; Rue Rigaud No. 64, Port-au-Prince, Haiti	1 February 1952
MARCEL, Fritz Gerald; Lieutenant	Haitian Armed Forces	Haiti	12 August 1964
MARCELIN, Eddy; Captain	Haitian Armed Forces	Haiti	20 May 1958
MARIUS, Hyppolite; Lieutenant	Haitian Armed Forces	Haiti	20 March 1957
MARIUS, Mireille; Lieutenant	Haitian Armed Forces	Haiti	5 May 1962
MARS, Briere; Captain	Haitian Armed Forces	Haiti	30 November 1954
MASSENA, Somner; Captain	Haitian Armed Forces	Haiti	7 June 1947
MASSENART, Boniface E.; Lieutenant	Haitian Armed Forces	Haiti	5 June 1957
MATHURIN, Frerot; Lieutenant Colonel	Haitian Armed Forces	Haiti	26 October 1950
MATHURIN, Ginette Perodin; Director	Ministry of Health, Unit for Potable Water	Montagne Noir, Impasse Monsieur Lafontant, Haiti; Passport No. 79-24143 (Haiti)	30 October 1953
MAURICE, Joël; Major	Haitian Armed Forces	Haiti	10 December 1953
MAURICE, Joseph François; Lieutenant	Haitian Armed Forces	Haiti	8 March 1946
MAXIME, Jean Miguelite; Lieutenant	Haitian Armed Forces	Haiti	28 October 1960
MAYARD, Henry (Henri) Max, Brigadier General	Haitian Armed Forces	Haiti	7 February 1947

Name/Rank	Organization	Identifying Information	Date of Birth
MAYARD–PAUL, Constantin		4 Rue E. Pierre, Pegueyville, Haiti	16 May 1930
McNALLY, Marie Lina; Deputy Director	Office d'Assurance Maladie/Accident	Haiti	6 March 1961
MEDACIER, Appolin; Major	Haitian Armed Forces	Haiti	4 October 1951
MEHU, Irving; Lieutenant Colonel	Haitian Armed Forces	Haiti	9 June 1954
MENARD, Jean–Emmanuel; Captain	Haitian Armed Forces	Haiti	26 April 1944
MENELAS, Jean Gael; Lieutenant	Haitian Armed Forces	Haiti	25 June 1960
MERILUS, Exantus; Lieutenant	Haitian Armed Forces	Haiti	15 February 1949
METELLUS, Marc Antoine; Lieutenant Colonel	Haitian Armed Forces	Haiti	18 November 1952
METELLUS, Smith; Senator	Haitian Parliament	Haiti	12 November 1933
MICHAUD, Eugene Henry; Lieutenant	Haitian Armed Forces	Haiti	4 November 1937
MICHEL, Fils; Lieutenant	Haitian Armed Forces	Haiti	31 May 1952
MICHEL, Francis; Lieutenant	Haitian Armed Forces	Haiti	25 December 1952
MICHEL, Fritz; Lieutenant	Haitian Armed Forces	Haiti	23 November 1960
MICHEL, Jean–Fritz; Lieutenant	Haitian Armed Forces	Haiti	9 October 1937
MICHEL, Joseph; Captain	Haitian Armed Forces	Haiti	15 October 1957
MICHEL, Marie José		Wife of Oriol Michel; Teina Village, P.O. Box 575–1, Port–au–Prince, Haiti	23 April 1942
MICHEL, Oriol; Director	Cement Company	Tecina Village, Cazeau, Port–au–Prince, Haiti; Passport No. 86–333255 (Haiti)	5 October 1946
MICHEL, Stanislas A.; Lieutenant	Haitian Armed Forces	Haiti	13 November 1940
MILORME, André; Lieutenant	Haitian Armed Forces	Haiti	17 March 1952
MINGOT, Marc; Lieutenant	Haitian Armed Forces	Haiti	17 October 1939
MINISTE, Yves Plaisimond; Lieutenant	Haitian Armed Forces	Haiti	15 August 1956
MITTON, Jacky; Captain	Haitian Armed Forces	Haiti	2 November 1957
MOMBES, Tessier; Lieutenant	Haitian Armed Forces	Haiti	22 January 1956
MOMPOINT, Fred Renaud; Lieutenant	Haitian Armed Forces	Haiti	7 October 1967
MOMPOINT, Herntz; Captain	Haitian Armed Forces	Haiti	25 May 1959
MONDELUS, Gilbert; Lieutenant	Haitian Armed Forces	Haiti	19 November 1953
MONDESIR, Brignol, Member	Chamber of Deputies of Haitian Parliament	Haiti	18 November 1953
MONFORT, Jean–Mathild; Lieutenant	Haitian Armed Forces	Haiti	24 November 1946
MONTHERVIL, Josue; Lieutenant	Haitian Armed Forces	Haiti	5 March 1959
MONUMA, Pradel J.; Major	Haitian Armed Forces	Haiti	17 April 1950
MOURRA, Jerry		Delmas 67, Port–au–Prince, Haiti	22 July 1959
MUSSET, Odius; Lieutenant	Haitian Armed Forces	Haiti	4 February 1950
NARCISSE, Margareth I.; Lieutenant	Haitian Armed Forces	Haiti	3 March 1962
NARCISSE, Maurice; Lieutenant	Haitian Armed Forces	Haiti	5 April 1952
NASSAR, Marie Elva S.; Lieutenant	Haitian Armed Forces	Haiti	10 October 1959
NELSON, Jean Thomas; Captain	Haitian Armed Forces	Haiti	1 June 1960
NEPTUNE, Pierre E.C.; Captain	Haitian Armed Forces	Haiti	25 May 1958
NEY–PIERRE, Arnold	Office d'Assurance Maladie/Accident	Avenue Nord Alexis 36, Port–au–Prince, Haiti	25 September 1929
NICOLAS, Carl Michel, General (retired)	Ministry of Interior and National Defense	Haiti	8 May 1937
NICOLAS, Marie Greta; Lieutenant	Haitian Armed Forces	Haiti	27 December 1949
NOAILLES, Joseph Willio; Minister	Ministry of Interior and National Defense	Haiti	4 December 1936
NOËL, Pierre Edriss; Lieutenant	Haitian Armed Forces	Haiti	22 March 1960
NORVILUS, Louis Appollon	Ministry of Health, Unit for Potable Water	Canapé Vert, Rue Jean Baptiste No. 47, Port–au–Prince, Haiti; Passport No. 83–95852 (Haiti)	6 May 1942
NORVILUS, Marie		Canapé Vert, Rue Jean Baptiste No. 47, Port–au–Prince, Haiti	20 February 1950
OCCENAD, Jean–Claude; Lieutenant Colonel	Haitian Armed Forces	Haiti	2 October 1955
OCCIL, Jean–Raymond; Lieutenant	Haitian Armed Forces	Haiti	23 May 1963
OLIVIER, Jean Wodchil; Lieutenant	Haitian Armed Forces	Haiti	16 August 1948
ORMILICE, Antoine O.P.; Lieutenant	Haitian Armed Forces	Haiti	13 July 1942
OVIL, Michel Jerome; Lieutenant	Haitian Armed Forces	Haiti	29 September 1960
OVILMAR, Sagesse; Lieutenant	Haitian Armed Forces	Haiti	20 February 1963
PASCAL, Jean Benes; Lieutenant	Haitian Armed Forces	Haiti	15 January 1952
PASCAL, José; Lieutenant	Haitian Armed Forces	Haiti	20 April 1949
PASCAL, Paul; Lieutenant	Haitian Armed Forces	Haiti	30 June 1951
PAUL, Benedict; Ensign	Haitian Armed Forces	Haiti	23 April 1962
PAUL, Mario; Lieutenant	Haitian Armed Forces	Haiti	2 August 1953
PAUL, Max; Director General	National Port Authority	Bourdon, Impasse Iginac No. 7, Haiti; La Saline Boulevard, P.O. Box 616, Port–au–Prince, Haiti; P.O. Box 1792, Port–au–Prince, Haiti; Passport No. 90–705113 (Haiti)	17 May 1945
PAUL, Normeus; Lieutenant	Haitian Armed Forces	Haiti	13 July 1936
PAUL, Patrick; Lieutenant	Haitian Armed Forces	Haiti	20 February 1963

Name/Rank	Organization	Identifying Information	Date of Birth
PAULEMON, Joseph Willy; Lieutenant	Haitian Armed Forces	Haiti	11 March 1942
PAULIN, Jean–Benito; Lieutenant	Haitian Armed Forces	Haiti	18 August 1947
PERMISSION, Jean Jacob; Lieutenant	Haitian Armed Forces	Haiti	15 January 1932
PETION, Mendes Lesly; Lieutenant	Haitian Armed Forces	Haiti	20 July 1960
PETIT–FRERE, Charles P.; Lieutenant	Haitian Armed Forces	Haiti	25 May 1939
PETIT–PHAT, Jean Marcel; Lieutenant	Haitian Armed Forces	Haiti	12 January 1958
PHILIPPE, Cruz Daniel; Colonel	Haitian Armed Forces	Haiti	3 May 1933
PHILIPPE, Jean–Luther; Lieutenant	Haitian Armed Forces	Haiti	26 July 1953
PHILIPPE, Leonard; Lieutenant	Haitian Armed Forces	Haiti	21 October 1941
PHILOGENE, Jacques Joseph; Major	Haitian Armed Forces	Haiti	30 December 1945
PIERRE, Bancks; Lieutenant	Haitian Armed Forces	Haiti	21 June 1947
PIERRE, Chevenel; Lieutenant	Haitian Armed Forces	Haiti	6 January 1960
PIERRE, Edward; Lieutenant	Haitian Armed Forces	Haiti	15 February 1961
PIERRE, Edwige; Captain	Haitian Armed Forces	Haiti	5 November 1958
PIERRE, Enelite; Lieutenant	Haitian Armed Forces	Haiti	27 October 1959
PIERRE, Jean Daniel; Captain	Haitian Armed Forces	Haiti	5 June 1959
PIERRE, Jean Palies; Lieutenant	Haitian Armed Forces	Haiti	16 January 1949
PIERRE, Jean Ulrick; Captain	Haitian Armed Forces	Haiti	4 October 1958
PIERRE, Jean Winel; Lieutenant	Haitian Armed Forces	Haiti	13 December 1951
PIERRE, Joachim; former Minister	Ministry of Social Affairs and Labor	Haiti	1938
PIERRE, Joseph Fils–Aimé; Lieutenant	Haitian Armed Forces	Haiti	8 February 1937
PIERRE, Joseph Reynold; Lieutenant	Haitian Armed Forces	Haiti	14 June 1947
PIERRE, Joseph Wistong; Lieutenant	Haitian Armed Forces	Haiti	1 September 1940
PIERRE, Luc; Lieutenant	Haitian Armed Forces	Haiti	26 May 1959
PIERRE, Marie Jessie; Lieutenant	Haitian Armed Forces	Haiti	27 August 1951
PIERRE, Patrick René; Captain	Haitian Armed Forces	Haiti	9 April 1960
PIERRE, Pierre Gérard; Major	Haitian Armed Forces	Haiti	19 July 1948
PIERRE, Raguel; Lieutenant	Haitian Armed Forces	Haiti	7 November 1940
PIERRE, Remy; Lieutenant Colonel	Haitian Armed Forces	Haiti	17 May 1947
PIERRE, René; Lieutenant	Haitian Armed Forces	Haiti	23 January 1938
PIERRE, Robert; Lieutenant	Haitian Armed Forces	Haiti	5 January 1966
PIERRE, Ulrick; Captain	Haitian Armed Forces	Haiti	15 November 1942
PIERRE–ANTOINE, Joseph; Colonel	Haitian Armed Forces	Haiti	19 March 1951
PIERRE–CHARLES, Frantz; Captain	Haitian Armed Forces	Haiti	27 February 1958
PIERRE–FILS, Aniceau; Lieutenant	Haitian Armed Forces	Haiti	6 October 1944
PIERRE–FILS, Israel; Lieutenant	Haitian Armed Forces	Haiti	18 September 1937
PIERRE–FRANÇOIS, Jean Dany; Captain	Haitian Armed Forces	Haiti	5 May 1960
PIERRE–FRANÇOIS, Marc–Henry; Captain	Haitian Armed Forces	Haiti	30 June 1961
PIERRE–JEROME, Gream Innocent; Lieutenant	Haitian Armed Forces	Haiti	28 October 1965
PIERRE–LOUIS, Claude A.J. Hervé (a.k.a. PIERRE–LOUIS, Jean Hervé)	Metropolitan Water Concern	Christ–Roi, Rue Mgr. Testard No. 6, Port–au–Prince, Haiti; Passport No. 81–159768 (Haiti)	12 February 1958
PIERRE–LOUIS, Hubert Michel; Captain	Haitian Armed Forces	Haiti	24 December 1952
PIERRE–PAUL, Edda; Lieutenant	Haitian Armed Forces	Haiti	1 December 1958
POISSON, Bernadin; Colonel	Haitian Armed Forces	Haiti	16 February 1948
POISSON, Bradley		Son of Col. Bernardin Poisson; Haiti	3 November 1976
POISSON, David		Son of Col. Bernardin Poisson; Haiti	20 November 1985
POISSON, Fabiola		Daughter of Col. Bernardin Poisson; Haiti	9 November 1980
POISSON, Ketia		Daughter of Col. Bernardin Poisson; Haiti	2 March 1974
POISSON, Marie Rose		Wife of Col. Bernardin Poisson; Haiti	7 March 1950
POULARD, Duval; Lieutenant	Haitian Armed Forces	Haiti	9 May 1957
PRATO, Nicolas A.; Lieutenant	Haitian Armed Forces	Haiti	4 July 1965
PREVAL, Alland; Lieutenant	Haitian Armed Forces	Haiti	3 September 1950
PROPHETE, Gérard; Lieutenant	Haitian Armed Forces	Haiti	21 December 1950
PROVINCE, Toxy; Lieutenant	Haitian Armed Forces	Haiti	26 July 1953
PRUD'HOMME, Ernst; Colonel	Haitian Armed Forces	Haiti	22 September 1954
PYRAM, Jean Emery; Lieutenant	Haitian Armed Forces	Haiti	14 June 1953
QUALO, Reginald	Télécommunications d'Haïti	Delmas 75 Angle Rue Catalpa et Mimosa, Port–au–Prince, Haiti; Passport No. 80–65056 (Haiti)	17 October 1953
RAPHAEL, François; Lieutenant Colonel	Haitian Armed Forces	Haiti	14 November 1943
RAGALA, William (a.k.a. REGALA, Williams)	Ministry of Interior and National Defense	Haiti	28 April 1937
RAPHAEL, Rigo; Captain	Haitian Armed Forces	Haiti	27 May 1941
RAVILUS, Raymond M.; Captain	Haitian Armed Forces	Haiti	17 March 1961
RAYMOND, Claude; former Minister	Ministry of Interior and National Defense	Haiti	14 April 1930
RAYNALD, Paul; Lieutenant	Haitian Armed Forces	Haiti	19 July 1938
REGALA, Williams (a.k.a. William RAGALA)	Ministry of Interior and National Defense	Haiti	28 April 1937

Name/Rank	Organization	Identifying Information	Date of Birth
REMEUS, Daniel; Lieutenant	Haitian Armed Forces	Haiti	2 December 1940
REMY, Jean Sergo; Lieutenant	Haitian Armed Forces	Haiti	11 April 1955
REMY, Jean–Luc; Lieutenant	Haitian Armed Forces	Haiti	6 June 1946
REMY, Jean–Thomas; Lieutenant	Haitian Armed Forces	Haiti	14 April 1948
RENAUD, Lener; Major	Haitian Armed Forces	Haiti	22 March 1956
RENÉ, Jacques; Lieutenant	Haitian Armed Forces	Haiti	8 March 1949
RENÉ, Jean–Nissage; Captain	Haitian Armed Forces	Haiti	29 December 1940
RENÉ, Jean Robert; Lieutenant Colonel	Haitian Armed Forces	Haiti	3 May 1953
RENÉ, Jean Roosevelt; Lieutenant	Haitian Armed Forces	Haiti	2 October 1966
RENÉ, Marie Alix; Colonel	Haitian Armed Forces	Haiti	28 July 1951
RENÉ, Paul Mercier; Lieutenant	Haitian Armed Forces	Haiti	12 September 1943
RENÉ, Yolette M.; Lieutenant	Haitian Armed Forces	Haiti	24 September 1952
REYME, Emmanuel; Member	Chamber of Deputies of Haitian Parliament	Haiti	12 June 1962
RICHARD, Denis; Lieutenant	Haitian Armed Forces	Haiti	2 March 1943
RICHARD, Louis–Marie M.; Lieutenant	Haitian Armed Forces	Haiti	15 June 1951
RICOT, Myrtho; Major	Haitian Armed Forces	Haiti	11 June 1937
RIGAUD, Max	Flour Company	Haiti	28 July 1921
ROBERT, Jean–Edwige; Lieutenant	Haitian Armed Forces	Haiti	15 August 1962
RODNEY, François Dukene; Captain	Haitian Armed Forces	Haiti	29 October 1958
ROLAND, Louis–Charles; Captain	Haitian Armed Forces	Haiti	18 September 1948
ROLLAND, Jean–Clausel; Major	Haitian Armed Forces	Haiti	23 April 1949
ROMAIN, Charles Poisset; Minister	Ministry of Education, Youth and Sports	Haiti	6 November 1940
ROMAIN, Franck		Haiti	29 January 1936
ROMAIN, Frank (François), Jr.		Son of Franck Romain; Haiti	11 September 1962
ROMAIN, Marie Rose		Wife of Franck Romain; Haiti	1 October 1939
ROMULUS, Dumarsais; Colonel	Haitian Armed Forces	Haiti	16 or 18 August 1948
ROMULUS, Jean Maceres; Captain	Haitian Armed Forces	Haiti	23 August 1957
ROMULUS, Martial P.; Colonel	Haitian Armed Forces	Haiti; 11903 Coronada Place, Kensington, MD 29895, U.S.A.; SSN 214–02–7585	26 February 1949
ROSARION, Jean Romann; Lieutenant	Haitian Armed Forces	Haiti	17 November 1967
ROSEMBERG, Yves Marie R; Captain	Haitian Armed Forces	Haiti	26 December 1955
ROUSSEAU, Jacques; Minister	Ministry of Public Works, Transportation and Communications	Haiti	10 November 1953
ROUSSEAU, Yves; Senator	Haitian Parliament	Haiti	2 October 1945
ROY, Chiller; Lieutenant	Haitian Armed Forces	Haiti	6 September 1964
SAIDEL, Jean Fricot; Lieutenant	Haitian Armed Forces	Haiti	14 May 1962
SAINT–ELOI, Inereste; Lieutenant	Haitian Armed Forces	Haiti	4 March 1945
SAINT–FLEUR, Alix–Robert; Lieutenant	Haitian Armed Forces	Haiti	12 May 1946
SAINT–FLEUR, Aristhote; Captain	Haitian Armed Forces	Haiti	22 May 1943
SAINT–FLEUR, Erick; Lieutenant	Haitian Armed Forces	Haiti	30 October 1960
SAINT–FLEUR, Jean; Lieutenant	Haitian Armed Forces	Haiti	28 June 1961
SAINT–FLEUR, Michaud; Major	Haitian Armed Forces	Haiti	1 December 1955
SAINT GERMAIN, Rubens; Lieutenant	Haitian Armed Forces	Haiti	2 May 63
SAINT–JEAN, Jonique; Lieutenant	Haitian Armed Forces	Haiti	3 October 1965
SAINT–JOY, Jean Armand; Major	Haitian Armed Forces	Haiti	7 November 1956
SAINT–JUSTE, Joseph; Lieutenant	Haitian Armed Forces	Haiti	10 March 1940
SAINT–LOUIS, Hervé; Lieutenant	Haitian Armed Forces	Haiti	10 July 1941
SAINT–LOUIS, Jacques N.; Lieutenant	Haitian Armed Forces	Haiti	5 December 1947
SAINT–LOUIS, Jacques Stanley; Lieutenant	Haitian Armed Forces	Haiti	7 March 1968
SAINT–PHAT, Cetelus; Lieutenant	Haitian Armed Forces	Haiti	20 April 1940
SAINT–PIERRE, Jean Claude; Lieutenant	Haitian Armed Forces	Haiti	28 October 1952
SAINT–PIERRE, Reynald; Lieutenant	Haitian Armed Forces	Haiti	29 August 1965
SAINT–VIL, Jean Adzor; Lieutenant	Haitian Armed Forces	Haiti	26 February 1949
SAINTIL, Agnes; Lieutenant	Haitian Armed Forces	Haiti	26 February 1945
SAINTIL, Sadrac; Colonel	Haitian Armed Forces	Haiti	29 January 1953
SAINTILAIRE, Joseph Odes; Lieutenant Colonel	Haitian Armed Forces	Haiti	4 February 1945
SAINVIL, Ramus; Colonel	Haitian Armed Forces	Delmas 68, Rue C. Henry No. 2, Port–au–Prince, Haiti; Passport No. 84–161640	15 September 1952
SALOMON, Gérard		Haiti	21 March 1954
SALOMON, Richard; Lieutenant	Haitian Armed Forces	Haiti	18 January 1960
SANON, Anthony; Lieutenant	Haitian Armed Forces	Haiti	18 June 1943
SANON, Mercidieu; Captain	Haitian Armed Forces	Haiti	27 June 1948
SANSARICQ, Bernard; President	Illegal Senate Bureau	Haiti; possible legal permanent resident of the United States	17 May 1944
SANZ, Joseph Lesly; Major	Haitian Armed Forces	Haiti	26 April 1953
SCOTT, Emmanuel E.L.E.; Lieutenant	Haitian Armed Forces	Haiti	3 March 1951
SEIDE, Ambroise Lucien; Captain	Haitian Armed Forces	Haiti	19 August 1952

Name/Rank	Organization	Identifying Information	Date of Birth
SHOUTE, Jean Michelet; Lieutenant	Haitian Armed Forces	Haiti	14 June 1960
SIMEON, Jean-Claude; Lieutenant	Haitian Armed Forces	Haiti	21 July 1943
SIMILIEN, Frito; Lieutenant	Haitian Armed Forces	Haiti	4 April 1947
SIMON, Estimien; Lieutenant Colonel	Haitian Armed Forces	Haiti	3 March 1941
SIMONISE, Jean-Robert	Ministry of Foreign Affairs	50 Rue Pacot, Port-au-Prince, Haiti	20 July 1955
SOUFFRANT, Yves Jean-Marie; Captain	Haitian Armed Forces	Haiti	11 October 1957
ST. DIC, Axel	Electricity Company	Rue Celcis No. 14, Canape Vert, Port-au-Prince, Haiti	31 January 1949
ST. FIRMIN, Jean	National Credit Bank	126 Impasse H. Samsour, Delmas 105, Port-au-Prince, Haiti; Passport No. 86-302061 (Haiti)	10 July 1934
ST-FLEUR, Jean; Lieutenant	Haitian Armed Forces	Haiti	28 June 1961
ST-FLEUR, Martial Raynald; Major	Haitian Armed Forces	Haiti	3 August 1948
ST-JULIEN, Adrien; Lieutenant	Haitian Armed Forces	Haiti	15 August 1937
SUPRIEN, Jean-Fleurant; Lieutenant	Haitian Armed Forces	Haiti	10 January 1953
SURIN, Gérard; Captain	Haitian Armed Forces	Haiti	1 February 1942
SYDNEUS, Damaxe; Colonel	Haitian Armed Forces	Haiti	10 April 1944
SYLVAIN, André; Lieutenant	Haitian Armed Forces	Haiti	4 October 1939
SYLVAIN, Diderot Lyonel (Lionel); Colonel	Haitian Armed Forces	Haiti	10 June 1950
TACHOUTE, Livingsma; Lieutenant	Haitian Armed Forces	Haiti	22 January 1953
TAMAR, Tanael; Lieutenant	Haitian Armed Forces	Haiti	4 January 1945
TELFORT, Adrien; Lieutenant	Haitian Armed Forces	Haiti	28 July 1949
TELUSMA, Joseph; Lieutenant	Haitian Armed Forces	Haiti	7 October 1954
THELISMA, Mac Gregor; Lieutenant	Haitian Armed Forces	Haiti	1 September 1968
THERANUS, Mario; Lieutenant	Haitian Armed Forces	Haiti	17 December 1966
THERLONGE, Jean-Claude; Lieutenant	Haitian Armed Forces	Haiti	15 December 1945
THIBAUD, Emmanuel; Lieutenant	Haitian Armed Forces	Haiti	15 June 1964
THOMAS, Joseph Jacques; Major	Haitian Armed Forces	Haiti	15 March 1955
THYBULLE, Alix		Haiti; U.S.A	27 September 1949
TIMO, Raynald; Captain	Haitian Armed Forces	Haiti	9 August 1957
TOUSSAINT, Henrio; Lieutenant	Haitian Armed Forces	Haiti	11 March 1962
TOUSSAINT, Ludovic P.; Lieutenant	Haitian Armed Forces	Haiti	17 July 1942
TOUSSAINT, Tacite; Lieutenant	Haitian Armed Forces	Haiti	2 March 1964
TRAVERSIERE, Jacques; Ensign	Haitian Armed Forces	Haiti	6 June 1945
TRECILE, Jean-Yonel; Lieutenant	Haitian Armed Forces	Haiti	22 December 1961
TUFFET, Jean-Victor; Lieutenant	Haitian Armed Forces	Haiti	24 September 1942
TURENNE, Jean Alfone; Lieutenant	Haitian Armed Forces	Haiti	16 March 1944
ULYSSE, Michaelle; Lieutenant	Haitian Armed Forces	Haiti	21 September 1962
VALET, Jean-Edmon, Leutenant	Haitian Armed Forces	Haiti	3 November 1941
VALET, Paul Ludovic; Lieutenant	Haitian Armed Forces	Haiti	13 June 1943
VALLES, Emmanuel A.M.J.; Captain	Haitian Armed Forces	Haiti	30 March 1956
VALME, Marc; Major	Haitian Armed Forces	Avenue Martin Luther King No. 152, Port-au-Prince, Haiti; Passport No. 81-142979	5 December 1953
VALMOND, Hebert; Colonel	Haitian Armed Forces	Haiti	17 May 1949
VELIA, Guy Gérard; Lieutenant	Haitian Armed Forces	Haiti	11 December 1949
VICTOR, Jean André	Ministry of Planning and External Cooperation	Haiti	10 September 1941
VILLARD, Montfort; Lieutenant	Haitian Armed Forces	Haiti	17 August 1948
VILME, Abner; Lieutenant	Haitian Armed Forces	Haiti	23 October 1964
VILSON, Lineau; Captain	Haitian Armed Forces	Haiti	24 March 1953
VOLTAIRE, Anatin O.; Lieutenant	Haitian Armed Forces	Haiti	15 September 1944
WAGNAC, Joseph Jean M.; Ensign	Haitian Armed Forces	Haiti	14 September 1962
WESTERBANDT, Adrien (a.k.a. WESTERBAND, Adrien)	Ministry of Public Health	Haiti	2 December 1924
WILLIAM, Donald G.; Lieutenant	Haitian Armed Forces	Haiti	18 January 1964
WILLIAMS, Nixon; Lieutenant	Haitian Armed Forces	Haiti	16 July 1964
WILSON, Eustache; Colonel	Haitian Armed Forces	Haiti	20 November 1942
YVON, Jules; Captain	Haitian Armed Forces	Haiti	16 March 1936
ZAMOR, Claudel; Captain	Haitian Armed Forces	Haiti	5 October 1960
ZAMOR, Jean Denis; Lieutenant	Haitian Armed Forces	Haiti	7 April 1962

II. Blocked Entities of the De Facto Regime in Haiti:

Organization	Address(es)
27TH COMPANY, FIRE DEPARTMENT (a.k.a. 27ÈME COMPAGNIE, CORPS POMPIER)	Haiti
ACCIDENT/INSURANCE OFFICE (a.k.a. OFFICE D'ASSURANCE MALADIE/ACCIDENT); (a.k.a. OFATMA); (a.k.a. WORKERS' COMPENSATION, SICKNESS AND MATERNITY INSURANCE AGENCY); (a.k.a. OFFICE D'ASSURANCE ACCIDENTS DU TRAVAIL, MALADIE ET MATERNITÉ)	Chancerelles – Cité Militaire, P.O. Box 1012, Port–au–Prince, Haiti.
BANK OF THE REPUBLIC OF HAITI (a.k.a. CENTRAL BANK OF HAITI); (a.k.a. BANQUE DE LA RÉPUBLIQUE D'HAÏTI); (a.k.a. BRH); (f.k.a. BANQUE NATIONALE DE LA RÉPUBLIQUE D'HAÏTI);	Angle rue du Magasin de l'État et rue des Miracles, BP 1570, Port–au–Prince, Haiti.
BANQUE POPULAIRE HAÏTIENNE (a.k.a. BPH)	Angle rues Eden et Quai, P.O. Box 1322, Port–au–Prince, Haiti
BUREAU OF THE INSPECTOR GENERAL SERVICE (a.k.a. BUREAU INSPECTEUR GÉNÉRALE, GRAND QUARTIER GÉNÉRALE (G.Q.G.))	Haiti.
CEMENT COMPANY (a.k.a. LE CIMENT D'HAÏTI, SA); (a.k.a. CDH)	Office Cité de l'Exposition, Port–au–Prince, Haiti; Fond Mombin, Port–au–Prince, Haiti.
CONSEIL NATIONAL DES TÉLÉCOMMUNICATIONS (a.k.a. CONATEL, a.k.a. TELECOMMUNICATIONS AGENCY)	16, Ave. Mie Jeanne, Cité de l'Exposition, P.O. Box 2002, Port–au–Prince, Haiti.
ELECTRICITY COMPANY (a.k.a. ÉLECTRICITÉ D'HAÏTI); (a.k.a. ELECTRICITY OF HAITI); (a.k.a. EDH)	Rue Dante Destouches, Port–au–Prince, Haiti; Boulevard Harry Truman, P.O. Box 1753, Port–au–Prince, Haiti.
FLOUR COMPANY (a.k.a. LA MINOTERIE D'HAÏTI); (a.k.a MDH)	Lafitteau, P.O. Box 404, Port–au–Prince, Haiti.
HAITIAN ARMED FORCES (a.k.a. FAD'H); (a.k.a. FORCE ARMÉE D'HAÏTI)	Haiti.
METROPOLITAN WATER CONCERN (a.k.a. WATER COMPANY); (a.k.a. CENTRALE AUTONOME MÉTROPOLITAINE D'EAU POTABLE); (a.k.a. CAMEP)	Paul VI Avenue 104, Port–au–Prince, Haiti.
MILITARY DEPARTMENT – ARTIBONITE REGION (a.k.a. DÉPARTEMENT MILITAIRE DE L'ARTIBONITE);	Haiti.
MILITARY DEPARTMENT OF THE METROPOLITAN ZONE (a.k.a. DÉPARTEMENT MILITAIRE DE LA ZONE MÉTROPOLITAINE); (a.k.a. COMET)	Haiti.
MINISTRY OF AGRICULTURE, NATURAL RESOURCES AND RURAL DEVELOPMENT (a.k.a. MINISTÈRE DE L'AGRICULTURE, DES RESSOURCES NATURELLES ET DU DÉVELOPPEMENT RURAL); (a.k.a. MARNDR)	Damien, Port–au–Prince, Haiti.
MINISTRY OF COMMERCE AND INDUSTRY	Rue Légitime, Champ de Mars, Port–au–Prince, Haiti.
MINISTRY OF ECONOMY AND FINANCE (a.k.a. MEF)	Palais des Ministères, Port–au–Prince, Haiti.
MINISTRY OF EDUCATION, YOUTH AND SPORTS (a.k.a. MENJS)	Boulevard Harry Truman, Cité de l'Exposition, Port–au–Prince, Haiti.
MINISTRY OF FOREIGN AFFAIRS AND WORSHIP	Boulevard Harry Truman, Cité de l'Exposition, Port–au–Prince, Haiti.
MINISTRY OF HEALTH, UNIT FOR POTABLE WATER (a.k.a. COMMUNITY HEALTH AND DRINKING WATER POSTS); (a.k.a. PROGRAMME DE SANTÉ DE L'EAU POTABLE); (a.k.a. POSTES COMMUNAUTAIRES D'HYGIÈNE ET D'EAU POTABLE); (a.k.a. POCHEP)	Petite Place Cazeau, P.O. Box 2580, Port–au–Prince, Haiti.
MINISTRY OF INFORMATION AND COORDINATION	300 route de Delmas, Port–au–Prince, Haiti.
MINISTRY OF INTERIOR AND NATIONAL DEFENSE (a.k.a. MINISTÈRE DE L'INTÉRIEUR ET DÉFENSE NATIONALE)	Palais des Ministères, Port–au–Prince, Haiti.
MINISTRY OF JUSTICE	Boulevard Harry S Truman, Cité de l'Exposition, Port–au–Prince, Haiti.
MINISTRY OF PLANNING AND EXTERNAL COOPERATION (a.k.a. MINISTÈRE DE LA PLANIFICATION ET COOPÉRATION EXTERNELLE)	Palais des Ministères, Rue Monseigneur Guilloux, Port–au–Prince, Haiti.
MINISTRY OF PUBLIC HEALTH (a.k.a. SANTÉ PUBLIQUE); (a.k.a. MINISTRY OF PUBLIC HEALTH AND POPULATION); (a.k.a. MINISTÈRE DE LA SANTÉ PUBLIQUE ET DE LA POPULATION); (a.k.a. MINISTRY OF PUBLIC HEALTH AND HOUSING)	Palais des Ministères, Port–au–Prince, Haiti.
MINISTRY OF PUBLIC WORKS, TRANSPORT AND COMMUNICATIONS (a.k.a. MINISTÈRE DES TRAVAUX PUBLICS, TRANSPORT ET COMMUNICATIONS); (a.k.a. MTPTC)	Palais des Ministères, BP 2002, Port–au–Prince, Haiti.
MINISTRY OF SOCIAL AFFAIRS	Rue de la Révolution, Port–au–Prince, Haiti.
NATIONAL AVIATION OFFICE (a.k.a. CIVIL AVIATION AUTHORITY, a.k.a. L'OFFICE D'AVIATION CIVILLE, a.k.a. OFNAC)	P.O. Box 1346, Port–au–Prince, Haiti.
NATIONAL CREDIT BANK (a.k.a. BANQUE NATIONALE DE CRÉDIT); (a.k.a. BANQUE COMMERCIALE D'HAÏTI); (a.k.a. BNC)	Angle rue du Quai et rue des Miracles, BP 1320, Port–au–Prince, Haiti; Place des Héros 21 Rue P. Quant, Port–au–Prince, Haiti.

Organization	Address(es)
NATIONAL INSURANCE (a.k.a. OLD AGE INSURANCE); (a.k.a. OFFICE NATIONAL D'ASSURANCE VIEILLESSE); (a.k.a. ONA)	Champ de Mars, Port–au–Prince, Haiti.
NATIONAL OFFICE FOR INDUSTRIAL PARKS (a.k.a. NATIONAL INDUSTRIAL PARK COMPANY);(a.k.a. GOVERNMENT INDUSTRIAL PARK); (a.k.a. SOCIÉTÉ NATIONALE DES PARCS INDUSTRIELS); (a.k.a. SONAPI)	Industrial Park, P.O. Box 2345, Port–au–Prince, Haiti.
NATIONAL PORT AUTHORITY (a.k.a. AUTORITÉ PORTUAIRE NATIONALE); (a.k.a. PORT AUTHORITY); (a.k.a. AIRPORT); (a.k.a. APN)	La Saline Boulevard, P.O. Box 616, Port–au–Prince, Haiti; P.O. Box 1792, Port–au–Prince, Haiti.
NATIONAL WATER SERVICE (a.k.a. SERVICE NATIONAL D'EAU POTABLE); (a.k.a. SNEP)	Delmas 45 – Delmas Road, Port–au–Prince, Haiti.
OFFICE FOR PERMANENT MAINTENANCE OF ROAD NETWORK (a.k.a. SERVICE D'ENTRETIEN PERMANENT DU RÉSEAU ROUTIER NATIONAL); (a.k.a. SERVICE D'ENTRETIEN DU RÉSEAU ROUTIER NATIONAL); (a.k.a. SEPRRN); (a.k.a. OFFICE OF ROAD MAINTENANCE)	Varreux – National Road, 10 Varreux Road, Port–au–Prince, Haiti.
OFFICE OF CUSTOMS (a.k.a. ADMINISTRATION GÉNERALE DES DOUANES)	161 Route de Delmas, Port–au–Prince, Haiti.
OFFICE OF MILITARY ATTACHES (a.k.a. BUREAU DES ATTACHÉS MILITAIRES)	Haiti.
TÉLÉNATIONALE D'HAÏTI (a.k.a. TÉLÉVISION NATIONALE D'HAÏTI)	Delmas 33, P.O. Box 13400, Port–au–Prince, Haiti.
TELEPHONE COMPANY (a.k.a. TÉLÉCOMMUNICATIONS D'HAÏTI, SAM); (a.k.a. TÉLÉCO)	J.J. Dessalines Boulevard, P.O. Box 814, Port–au–Prince, Haiti.

Dated: October 4, 1994

Steven I. Pinter,

Acting Director, Office of Foreign Assets Control.

Approved: October 4, 1994

R. Richard Newcomb,

Acting Deputy Assistant Secretary (Law Enforcement).

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