to the Secretary by statute, to determine which costs are reasonable and related to the efficient delivery of health care to Medicare beneficiaries, the determination has been made that a nursing cost differential is no longer appropriate as an allowable cost and reimbursable cost under the Medicare program.

A number of editorial changes have been made in the interest of clarity. With these changes, the proposed amendment is adopted and set forth below.

(Secs. 1102, 1814(b), 1861(v)(1)(A), 1871, Social Security Act, 49 Stat. 647, as amended, 79 Stat. 296, as amended, 79 Stat. 322, as amended, and 79 Stat. 331; 42 U.S.C. 1302, 1395f(b), 1395x(v)(1)(A), and 1395hh.)

Effective date: This regulation will be effective June 23, 1975, and will be effective for cost-reporting periods beginning after June, 1975.

(Catalog of Federal Domestic Assistance Program No. 13.800, Health Insurance for the Aged—Hospital Insurance.)

Dated: May 13, 1975.

J. B. CARDWELL,
Commissioner of Social Security.

Approved: May 19, 1975.

CASPAR W. WEINBERGER,
Secretary of Health, Education, and Welfare.

Regulations No. 5 of the Social Security Administration (20 CFR Part 405) is further amended as set forth below:

Section 405.430 is amended by revising paragraphs (a), (c)(1), and (d)(1) and (2), and the title of paragraph (e)(1) to read as follows:

§ 405.430 Inpatient routine nursing salary cost differential.

(a) *Principle.* In recognition of the above-average cost of inpatient routine nursing care furnished to aged patients, an inpatient routine nursing salary cost differential is allowable as a reimbursable cost of a provider after June 30, 1969, and before that provider's first cost-reporting period which begins after June 1975 (the month after publication in the FEDERAL REGISTER). The allowable differential applicable to such inpatient routine nursing salary costs of aged patients for the specified period is reimbursable at the rate of 8½ percent. Recognition of the differential by the health insurance program is accomplished through an inpatient routine nursing salary cost differential adjustment factor as defined in paragraph (b) (8) of this section.

* * * * *

(c) *Application.* (1) In the determination of health insurance inpatient routine service costs, the rate of 8½ percent has been established as the inpatient routine nursing salary cost differential for aged, pediatric, and maternity patients. This inpatient routine nursing salary cost differential is applicable to inpatient routine nursing salary costs incurred by a provider after June 30, 1969, and before that provider's first cost-reporting period which begins after June 1975 (the month after publication in the FEDERAL REGISTER).

* * * * *

(d) *Effective dates.* (1) *Cost-reporting periods beginning after June 30, 1969, and before July 1975* (the second month after publication in the FEDERAL REGISTER). For cost-reporting periods beginning after June 30, 1969, and before July 1975 (the second month after publication in the FEDERAL REGISTER). The inpatient routine nursing salary cost differential adjustment factor is applicable for the entire reporting period as an element in the computation of the provider's reimbursable cost.

(2) *Cost-reporting periods ending before July 1, 1969, or cost-reporting periods beginning after June 1975* (the month after publication in the FEDERAL REGISTER). For cost-reporting periods ending before July 1, 1969, or cost-reporting periods beginning after June 1975 (the month after publication in the FEDERAL REGISTER). There shall not be included as an element in the computation of the provider's reimbursable costs any inpatient routine nursing salary cost differential adjustment factor.

* * * * *

(e) *Examples.* (1) *Illustration of calculation of differential adjustment factor for a cost-reporting period beginning after June 30, 1969, and before July 1975* (the second month after publication in the FEDERAL REGISTER).

* * * * *

[FR Doc.75-13621 Filed 5-22-75;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 37—FISH

Canned Pacific Salmon; Order Amending Standards of Identity and Fill of Container

The Commissioner of Food and Drugs is amending the standards of identity (21 CFR 37.10) and fill of container (21 CFR 37.12) requirements for canned Pacific salmon, effective July 22, 1975, except as to any provisions that may be stayed by the filing of proper objections. Objections to this order may be filed on or before June 23, 1975. The Commissioner originally proposed the amendments in a notice of proposed rule making published in the FEDERAL REGISTER of May 29, 1974 (39 FR 18660), to adopt, as far as is practicable, the provisions of the Recommended International Standard for Canned Pacific Salmon (Codex).

Three additional forms of canned salmon are being added to the identity standard—"Minced Salmon," "Salmon Tips or Tidbits," and a "No Salt Added" form. Based on the Codex standard, a sampling plan and related definitions have been added to the present fill of container standard.

One letter from a trade association and one from a consumer organization, each letter containing five comments, were received in response to the proposal. These comments and the Commissioner's conclusions based on his evaluation of them are as follows:

1. One comment opposed including the optional forms "Minced Salmon" and "Salmon Tips or Tidbits" (§ 37.10 (c)(3) and (c)(4)) until the proper technology for handling the edible parts of the trimmings can be developed. The comment also stated that § 37.10(c) would have to be revised to provide for the use of edible parts of the trimmings.

The Commissioner notes that "Minced Salmon" and "Salmon Tips or Tidbits" are recognized articles of commerce in the world market. The present standard as amended herein is sufficiently broad to embrace present technology, to permit development of improved product technologies, and to provide for use of any edible portions of salmon flesh in the products with appropriate labeling. The Commissioner concludes that it will benefit the consumer and facilitate world trade to provide for these forms of canned salmon at this time.

2. One comment opposed the term "minced" in § 37.10(c)(3), stating that it is not as familiar to the consumer as the term "flaked."

The Commissioner concludes that the term "minced" more accurately describes the form of the salmon product than the term "flaked" and considers the term "minced" appropriate for the product. Consumers are probably most familiar with the term "flaked" as one of the standardized forms of canned tuna. On tuna cans it refers to a mixture of tuna pieces of such size that more than 50 percent of the pieces will pass through a ½-inch mesh screen and also retain the muscular structure of the flesh. The term "minced" refers to finely ground particles.

3. One comment requested that the Codex canned salmon style "No Salt Added" be provided for in the U.S. identity standard. The comment stated in support of this request that about 10,000 to 20,000 cases of unsalted canned salmon are produced each year. The comment explained that the product is provided for in the Interim Federal Specification for Canned Salmon, PP-S-31c, and that the principal recipients of this product are government agencies. Another comment stated that it is misleading to label canned salmon with the words "No Salt Added" because of the implication that the product is a low sodium food. In addition, the comment stated that a regulation should be promulgated stating that it is misleading to emphasize the absence of added salt in a product not naturally low in sodium.

In view of the apparent market for unsalted canned salmon, the Commissioner concludes that it would be in the consumers' interest to permit the label of canned salmon packed without the addition of salt to bear a statement to that effect. Such labeling will not be misleading, provided the label statements required by § 125.9 *Label statements relating to food for use as a means of regu-*

lating the intake of sodium (21 CFR 125.9) appear on the label regarding any statement describing the absence of added salt. The regulation below has been changed accordingly.

The Commissioner also concludes that a regulation for misleading labeling of food products not naturally low in sodium is a separate issue that should be a separate proposal dealing with all food.

4. One comment urged that provision be made for various packing media, such as water, vegetable broth, and a combination of oil and broth.

The Commissioner notes that the natural charactertistics of the six species of Pacific salmon are such that the food may be processed without precooking or without the addition of various packing media. The Commissioner concludes that to permit the addition of unnecessary packing media to canned salmon is not in the consumers' interest, and the order does not provide for the use of packing media. Salmon oil added to canned salmon is not considered to be a packing medium because of the very small amounts used (about 3 to 6 ml of oil per can).

5. One comment stated that the last sentence in § 37.10(e)(2) (21 CFR 37.10 (e)(2)) in the present identity standard should be retained. The comment maintained that deletion of the sentence would necessitate making the type size for the form of pack the same size as that for the name of the food.

The Commissioner agrees that the wording in the proposal may be unclear and has reworded the paragraph. He did not intend that the statement of form must be the same size as the words in the name of the food. Accordingly, the regulation has been revised to incorporate by reference the requirements of 21 CFR 1.8(c).

6. One comment asserted that the number of samples required by proposed § 37.12(b) to calculate the average net weight is too large; it would result in economic loss due to the high cost of salmon.

The Commissioner concludes that the basis of the sample size requirement is statistically sound and is necessary to assure the proper average net weight of the product.

7. One comment stated that the incorporation of a sampling plan into the standard should be considered in a separate publication. It also stated that "It is particularly egregious to incorporate a sampling plan into the canned salmon regulation without modifying the acceptable minimum net weights for the various can sizes. Under the existing standard each can must meet the minimum net weight, and so packers must pack above the minimum amounts on the average to assure compliance. By adding the sampling plan without raising the requirements the FDA is allowing a lower average to be packed into each can, a distinct disservice to the consumer."

The Commissioner agrees that the problem of sampling plans is complex; it should not be resolved solely upon the comments of a few persons interested only in a particular commodity. The sampling plans in the proposed amendment are the result of years of study by many individuals and groups. The applicability of the plans is well established and accepted. Sampling plans are essential to proper determination of compliance with the requirements of a fill of container standard.

The statement in the comment that the applicable provision of the present fill standard requires that each can must meet the minimum fill requirement is in error. The present § 37.12(a) (21 CFR 37.12(a)) states that the standard of fill for canned salmon is based on a 24-can average weight of the contents of the cans making up the sample.

The Commissioner concludes that the proposed amendment of § 37.12(a) is in the consumers' interest, and there is no reason to publish the sampling plan as a separate proposal.

8. One comment opposed the listing of packing oil in the net weight statement of the product and stated that the quantity of contents in the can should be declared on the label as drained weight.

The Commissioner advises that the practice of adding salmon oil to canned salmon is limited to a small percentage of the pack of three species of salmon, usually to ¼- and ½-pound can sizes, and to very small amounts (about 3 to 6 ml of oil per can). The practice is self-limiting for a number of reasons, not the least of which is that the cost of salmon oil is greater than the cost of salmon.

The Commissioner concludes that it is reasonable to include the weight of the added salmon oil in the quantity of contents statement because added salmon oil is an edible part of the food and, since no packing media are permitted, to declare the quantity of contents of canned salmon as net weight.

9. One comment stated that it was assumed that the minimum weight column in the proposed regulation (§ 37.12(a)) giving metric equivalents of the U.S. customary system units is for informational purposes and not required for labeling.

The Commissioner affirms this assumption. At the present time, labeling information in metric units is not required. However, the Commissioner encourages the use of contents declarations in terms of the International (metric) System along with the U.S. customary system.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055–1056, as amended, 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371)) and under authority delegated to the Commissioner (21 CFR 2.120): *It is ordered*, That 21 CFR Part 37 be amended as follows:

1. In § 37.10 by adding new paragraph (c) (3), (4), and (5) and revising paragraph (e) (2) and (3) to read as follows:

§ 37.10 Canned Pacific salmon; identity.

* * * * *

(c) * * *

(3) "Minced Salmon" consists of salmon which has been minced or ground.

(4) "Salmon Tips or Tidbits" consists of small pieces of salmon.

(5) "No Salt Added" consists of canned salmon to which no salt has been added.

* * * * *

(e) * * *

(2) (i) Whenever the form of pack is that described in paragraph (c) (2), (3), or (4) of this section, the word or words describing the form of pack shall immediately precede or follow the name of the food without intervening written, printed, or graphic matter in the manner prescribed in § 1.8(c) of this chapter; for example, "red salmon" as the name of the food followed by "skinless and backbone removed."

(ii) Whenever the form of pack is that described in paragraph (c)(5) of this section and words describing the form of pack are declared on the label, the label shall also bear the statements required by § 125.9 of this chapter.

(3) The name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

2. By revising § 37.12 to read as follows:

§ 37.12 Canned Pacific salmon, fill of container; label statement of substandard fill.

(a) The standard of fill of container for canned salmon is a fill including all the contents of the container and is not less than the minimum net weight specified for the corresponding can size in the following table:

I. *Can size*	II. *Minimum net weight*
603x405	1.814 kg (64 oz).
301x411	454 g (16 oz).
301x408	439 g (15½ oz).
401x211	439 g (15½ oz).
607x406x108	439 g (15½ oz).
301x308	340 g (12 oz).
307x200.25	220 g (7¾ oz).
513x307x103	220 g (7¾ oz).
307x113	191 g (6¾ oz).
301x106	106 g (3¾ oz).
407x213x015	106 g (3¾ oz).

If the can size in question is not listed, calculate the value for Column II as follows: From the list, select as the comparable can size, that one having the nearest water capacity of the can size in question, multiply the net weight listed in Column II by the water capacity of the can size in question, and divide by the water capacity of the comparable can size. Water capacities are determined by the general method provided in § 10.6 (a) of this chapter.

(b) Sampling and acceptance procedure: The sample size of the sample representing the lot will be selected in accordance with the sampling plan shown in paragraph (b)(2) of this section. A lot is to be considered acceptable when the average net weight of all the sample units is not less than the minimum net weight stated in paragraph (a) of this section for the corresponding can size.

(1) Definitions of terms to be used in the sampling plans in paragraph (b)(2) of this section are as follows:

(i) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(ii) *Lot size.* The number of primary containers or units in the lot.

(iii) *Sample size (n).* The total number of sample units drawn for examination from a lot.

(iv) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for examination or testing as a single unit.

(2) Sampling plans:

Lot size (primary containers):	*Size of container*[1] *(n)*
4,800 or less	13
4,801 to 24,000	21
24,001 to 48,000	29
48,001 to 84,000	48
84,001 to 144,000	84
144,001 to 240,000	126
Over 240,000	200

[1] Net weight equal to or less than 1 kg. (2.2 lb).

Lot size (primary containers):	*Size of container*[1] *(n)*
2,400 or less	13
2,401 to 15,000	21
15,001 to 24,000	29
24,001 to 42,000	48
42,001 to 72,000	84
72,001 to 120,000	126
Over 120,000	200

[1] Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kgs (10 lb).

(c) If canned salmon falls below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.7(b) of this chapter, in the manner and form therein specified.

Any person who will be adversely affected by the foregoing order may at any time on or before June 23, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective on July 22, 1975, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1046, 1055-1056, as amended, 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371))

Dated: May 15, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-13546 Filed 5-22-75;8:45 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 331—ANTACID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Revised Effective Dates

The Commissioner of Food and Drugs is extending the effective date to September 2, 1975 for labeling of antacid and antiflatulent products not receiving an extension of the effective date for reformulation.

In the FEDERAL REGISTER of June 4, 1974 (39 FR 19862), the Commissioner promulgated a final order for antacid and antiflatulent Over-the-Counter (OTC) products generally recognized as safe and effective and not misbranded. Paragraph 82 of the preamble of that order states that the Commissioner concluded that it was reasonable to establish the following conditions for the effective date of the final monograph: "The effective date of the monograph will be July 5, 1974, with the following exceptions. The effective date for all labeling for products not receiving an extension of the effective date for reformulation shall be June 5, 1975. Where reformulation is necessary, and if sufficient data and reasons are supplied, the Commissioner will grant an extension of the effective date for reformulation and relabeling for up to 2 years after the date of publication in the FEDERAL REGISTER."

The Commissioner has received requests and petitions from major manufacturers of OTC antacid products and from a trade association requesting that the effective date for all labeling for products not receiving an extension for reformulation be extended beyond June 5, 1975.

One trade association has petitioned to allow an orderly inclusion of the general warning statement required by § 330.1(g) (21 CFR 330.1(g)) of the regulations and has commented on the recent change in that warning published in the FEDERAL REGISTER of March 13, 1975 (40 FR 11717). It was noted that in order to comply with the June 5, 1975 effective date for the antacid and antiflatulent monographs, many OTC antacid and antiflatulent manufacturers have ordered, received, and in some instances, affixed to the container the labeling for their antacid and antiflatulent products, but because of the changes in the general warning published recently, these same manufacturers do not have either the exact language on their current stocks of labeling, or due to the uncertainty of the adoption and specific language of the regulation prior to publication, do not have any similar language on their labeling. Therefore, it was petitioned that manufacturers and distributors who have already ordered and received such labeling be allowed to use labeling stock that otherwise complied with the monographs and to include the general warning required by § 330.1(g) in their next labeling order.

There was comment from manufacturers that, due to severe shortages besetting the paper industry and uncertainties arising from the energy crisis, stocks and labeling had to be ordered in greater quantities and that an unanticipated sharp downswing in the economy has aggravated the over-supply situation of such stocks and labeling. It was noted that destruction of this substantial amount of stock would create a severe financial hardship for the companies and would not be in the public interest. Therefore, it was petitioned that the effective date of the final order be stayed for a period of 4 to 6 months.

The Commissioner concludes that there are valid reasons to allow an extension beyond June 4, 1975 of the effective date of the OTC antacid and antiflatulent monographs. First the Commissioner concludes that the March 13, 1975 publication in the FEDERAL REGISTER of the final order for the general warning (40 FR 11717) did not provide sufficient time for including the general warning statement required by § 330.1(g) and that labeling which otherwise complies with the monograph should be used until new labeling is ordered.

The Commissioner is also aware that in some instances a downward trend in the economic picture may have resulted in an overstock situation. The Commissioner agrees that for the companies this condition would create an economic waste, the cost of which would ultimately be passed on to the consumer which would not be in the public interest.

However, taking into consideration all of the reasons given for an extension of time of the effective date of the OTC antacid and antiflatulent monographs, the Commissioner concludes that it is not in the best interest of the consumer to allow an indefinite period of time to elapse before requiring all manufacturers and distributors to be in compliance with the monographs. Accordingly, he has determined that a 90-day extension for compliance shall be provided for those products for which there is no extension of the effective date for reformulation. The revised effective date for all labeling for these products shall be September 2, 1975.

Recognizing that there has been only a short period of time since the general warning final order of March 13, 1975 was published, the Commissioner additionally concludes that, if there is compliance with the labeling requirements of the antacid and antiflatulent monographs in all other respects at the end of the 90-day extension period, manufacturers and distributors should be permitted to use labeling stock and include

the general warning revision in their next labeling order.

The Commissioner concludes that the extension does not affect the effective date, where an extension has been granted for reformulation and relabeling.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetics Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)), (5 U.S.C. 553, 554, 702, 703, 704) and under authority delegated to the Commissioner (21 CFR 2.120), the effective dates for 21 CFR Parts 331 and 332 are revised as follows:

Effective date. All labeling for products not receiving an extension of the effective date for reformulation shall become effective on September 2, 1975, and where reformulation is necessary and an extension is granted the labeling requirements shall become effective on June 4, 1976.

Since the amendment established by this order grants relief of a restriction, namely the June 4, 1975 effective date previously published, notice and public procedure and delayed effective date are not prerequisites to this promulgation.

Effective date: This order shall be effective on May 23, 1975.

(Secs. 201, 502, 505, 701, Pub. L. 717, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371); (5 U.S.C. 553, 554, 702, 703, 704))

Dated: May 19, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-13578 Filed 5-22-75;8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

Change in Sponsor

Correction

In FR Doc. 75-11385 appearing on page 18993 in the issue for Thursday, May 1, 1975, in § 510.600(c)(2) the second and third lines of Drug listing No. 000381 should be reversed.

SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

PART 1240—CONTROL OF COMMUNICABLE DISEASES

Ban on Sale and Distribution of Small Turtles

An order published in the FEDERAL REGISTER of November 18, 1972 (37 FR 24670) amended Parts 71 and 72 of Title 42, Code of Federal Regulations, by establishing §§ 71.171 through 71.176 (42 CFR 71.171 through 71.176) which provide for a general prohibition on the importation of certain small pet turtles and viable turtle eggs, and § 72.26 (42 CFR 72.26) (now § 1240.62 (21 CFR 1240.62) pursuant to transfer and recodification of the sections of 42 CFR Part 72 appropriate to Food and Drug function, published in the FEDERAL REGISTER of February 6, 1975 (40 FR 5620)) which required that pet turtles shipped in interstate commerce be tested for and certified free of *Salmonella* and *Arizona* organisms by the appropriate public health officials in the State of origin. The order was based upon epidemiological investigations that have shown that small pet turtles are a particularly significant source and reservoir of bacteria of the genera *Salmonella* and *Arizona*, both of which can cause, among other things, acute gastrointestinal illness in humans. Data and other information on the hazards of such bacteria and on the extent of turtle-associated disease are on display in the office of the Hearing Clerk.

There is continuing evidence, however, that the certification requirements have had limited effectiveness in preventing contaminated turtles from reaching pet owners. Although the certification program appears to have curtailed the number of turtles being shipped in interstate commerce, a recent survey of turtles certified between December 1972 and December 1973 completed by the Public Health Service Center for Disease Control shows that 54 percent of the turtles were contaminated by *Salmonella* and *Arizona* when retested some time subsequent to certification. The State of New Jersey has sampled six lots of turtles shipped to that State and detected *Salmonella* in five of the lots. Furthermore, the Food and Drug Administration has taken five selective samples of turtles certified by State health authorities and found *Salmonella* and *Arizona* organisms in three of the five samples. Four out of the five selected water samples in which turtles have been held were positive for *Salmonella*. Moreover, the Center for Disease Control has reported cases of salmonellosis in California, Oregon, and Tennessee associated with turtles from certified lots.

As recently as August 19, 1974, a batch of approximately 16,000 turtles was certified by the Louisiana State Department of Health as *Salmonella*- and *Arizona*-free. A sample collected from this same lot of 16,000 turtles on inspection August 21 and 22, 1974, in Pierre Part, Louisiana, was later found by the Dallas Laboratory of the Food and Drug Administration to be positive for *Arizona*. Three official samples were collected and analyzed from interstate shipments of this lot of turtles. All samples were subsequently found to be positive for *Arizona*. On October 18, 1974, the Food and Drug Administration undertook to issue Letters of Demand for Destruction by its district offices to all dealers handling turtles from this lot.

Prior to this most recent action against certified but contaminated turtles, the Commissioner of Food and Drugs, realizing that the present certification program was not preventing contaminated turtles from reaching the market, issued two proposals published in the FEDERAL REGISTER of May 28, 1974 (39 FR 18463) for consideration as possible solutions to the contaminated turtle problem: first, a complete ban on the sale and distribution of small turtles and, second, improvement of the certification scheme with imposition of additional requirements on the sale and shipment of turtles.

The preamble to those proposals pointed out that studies of salmonellosis have resulted in estimates that 14 percent of all human cases of salmonellosis are turtle-associated. It is thus possible that as many as 280,000 of the estimated 2,000,000 cases of salmonellosis in the United States each year are turtle-related.

Children are particularly susceptible to salmonellosis, tend to have more severe cases than adults, and are subject to infection transmitted when playing with pet turtles.

Finally, it was pointed out by the Animal Welfare Institute that small turtles sold in pet shops are not miniature, but baby turtles, mostly red-eared sliders, which under proper care can attain a shell length ranging from 6 to 11 inches and can live more than 40 years in captivity; yet 90 percent of the pets survive only 4 to 6 months.

Two hundred and forty-eight comments were received in response to the proposals from individual citizens, members of Congress, Federal, State and local officials, consumer groups, educational institutions, industry and professional groups, and turtle fanciers and their associations. Thirty-four comments opposed both proposals. Thirty-seven comments endorsed the improvement of the certification scheme and the imposition of additional requirements on the sale and shipment of turtles and turtle eggs. An additional comment opposing the ban addressed the statistical relationship between turtle ownership and its impact on human salmonellosis. One hundred and twenty-eight comments endorsed the proposal banning sale of small turtles. An additional comment endorsing the ban suggested that the ban include all turtles regardless of size or species and that a permit from the Commissioner be required by the purchaser before an exemption will be granted for bona fide scientific, educational, or exhibitional purposes. Two comments did not believe that the improvement of the certification scheme and the imposition of additional requirements on the sale and shipment of small turtles would be effective in dealing with the existing public health hazard. Ten comments requested that the sale of pet turtles be prohibited until the turtle industry demonstrates its ability to produce *Salmonella*- and *Arizona*-free turtles. Two comments requested a moratorium of 1 year on the banning of turtles from the market so that a study could be made to determine whether *Salmonella*- and *Arizona*-free turtles can be produced. Twenty-two

comments requested modification of the total ban proposal. The remaining eleven comments did not address themselves to the published proposals.

The Commissioner has evaluated all the comments. The issues raised and the Commissioner's responses are as follows:

1. Thirty-four comments expressed the opinion that any restrictions on the shipment, sale, or distribution of turtles would be an infringement on a person's constitutional right to possess the pet of his choice.

The Commissioner does not agree that individuals have an absolute right to possess any pet they wish to own. The individual's right to possess that pet must be weighed against the public hazard which may be created by allowing the sale of pets which may be contaminated with organisms dangerous to human health. *Salmonella* and *Arizona* organisms create human health hazards and are directly associated with small pet turtles. Documented evidence exists that such organisms accompany turtles even after they have been certified "*Salmonella*- and *Arizona*-free" using methods prescribed by § 1240.62. Therefore, the individual's right to purchase turtles must be measured against the known hazard to the health and welfare of the public as a result of their being offered for sale. Salmonellosis can be a serious disease, particularly in childhood, and can lead to death. Further, small children, for whom most pet turtles are purchased, cannot be expected to understand the reasons for, or abide by, sanitary measures that might protect them from illness.

Finally, in view of the nature of this particular comment, and also because of his wish to seek their advice on the entire matter, the Commissioner presented the issue to FDA's National Advisory Food and Drug Committee during their meeting of March 28, 1975. After consideration of this and other comments and after arguing the risk/benefit considerations of a ban on turtle sales vs. a more elaborate certification program, the Committee voted 19 to 3 to support a ban on sales. The Committee further agreed with the comment that the entire matter should be reconsidered if research demonstrates means whereby turtles could be kept *Salmonella*- and *Arizona*-free.

2. Thirty-seven comments endorsed the improvement of the certification scheme and the imposition of additional requirements on the sale and shipment of turtles and turtle eggs. Some of the comments opposed a direct ban on the sale and distribution of small turtles and supported the improved certification scheme as a preferable approach to control the public health problems associated with turtles. No evidence was presented by the comments, however, nor is the Commissioner presently aware of any evidence, that demonstrates that an improved certification scheme would result in a *Salmonella*- and *Arizona*-free turtle that will remain free of these organisms in commerce.

Therefore, the Commissioner, basing his decision on previous investigations and the failure of comments to present any evidence to the contrary, concludes that the improved certification scheme would be ineffective.

3. Several of the above comments, although supporting the improved certification scheme, opposed the proposed written warnings to be given with each pet turtle at sale until other *Salmonella*-susceptible animals or products are subject to similar requirements.

The Commissioner concludes that assessment of the written warning requirements will not be necessary since the ban proposal, not the improved certification proposal, will be implemented.

4. One comment opposing the ban addressed the statistical relationship between turtle ownership and its impact on human salmonellosis. It questioned the reliability of the article by Steven H. Lamm et al., "Turtle-Associated Salmonellosis," *American Journal of Epidemiology*, 95.511 (1972). It was pointed out that even though there has been a drastic decrease in the number of turtles sold and shipped in the United States since 1972, reports of the isolation of *Salmonella* organisms in humans have continued to rise. Statistics were also quoted from the New Jersey Department of Health which indicated that the cases of salmonellosis reported in the year following the ban on the sale of turtles in that State were almost 50 percent higher than the 2 preceding years combined.

The Commissioner advises that salmonellosis infection derives from many different sources, one of which is turtles. Moreover, the reporting of cases of salmonellosis may vary significantly, at different times, even in the same State. The data quoted above simply reflect those facts. There is no assurance that a reduction of the number of turtles sold in a given year will, in all circumstances, result in a reduction in the number of reported cases of salmonellosis infection.

Since it has previously been established that turtles are a significant source of *Salmonella* contamination and evidence has not been presented that demonstrates otherwise, the Commissioner concludes that turtles should be prohibited from general sale.

5. One hundred and twenty-eight comments endorsed the ban proposal.

The Commissioner agrees that a total ban with the exceptions provided by § 1240.62(d) is the only effective method at the present time that will eliminate the possibility of human illness due to contaminated turtles since there was no evidence presented which demonstrated that an improved certification scheme and written warnings at the time of sale would effectively control the *Salmonella* and *Arizona* problem.

The Commissioner also notes that thirty-one State agencies responded to the two proposals and only one State was opposed to the banning of small turtles for sale and distribution. The remaining thirty States, as well as seventeen individual comments, favored the ban since they concluded that the present certification program is inadequate and that it is unlikely that an improved certification scheme, which could well be cumbersome and expensive, would be completely effective.

However, the Commissioner will at any time in the future consider evidence presented to him which demonstrates that *Salmonella*- and *Arizona*-free turtles can be produced and that sufficient safeguards exist to prevent a public health hazard through recontamination of turtles after shipment.

6. An additional comment favoring the ban proposed that the ban should include all turtles regardless of size or species.

The Commissioner concludes that since the turtles with a carapace, i.e., upper shell, length of less than 4 inches are the more common pet varieties purchased for or by children, the ban should not be extended to include turtles whose carapace is larger than 4 inches. The sole objective of this regulation is to protect the public, primarily children, from contaminated pet turtles. The Commissioner believes that the present size limitation adequately provides this protection. The Commissioner wishes to emphasize, however, that if sufficient evidence is presented that demonstrates that turtles with a carapace of more than 4 inches are a public health hazard, the ban will be exetnded to include the larger turtles.

7. The preceding comment also suggested that a permit from the Commissioner be required before an exemption will be granted for purchasing live turtles and viable turtle eggs used for bona fide scientific, educational, or exhibitional purposes, other than use as pets.

The Commissioner concludes that the interstate shipment of live turtles and viable turtle eggs used for bona fide scientific, educational, or exhibitional purposes will be allowed without the obtaining of a permit.

The Commissioner concludes that these exceptions would not constitute a significant hazard to public health due to the limited accessibility of the general public to turtles used for these particular purposes. Furthermore, the Commissioner does not believe that these exceptions justify the establishment of an elaborate permit program requiring the deployment of scarce manpower and funds.

8. Two comments were received which expressed the opinion that the improvement of the certification scheme and the imposition of additional requirements on the sale and shipment of pet turtles would be ineffective to deal with the public health hazard since subsequent handling could easily result in reinfection and the concomitant risks of human disease.

The Commissioner is in agreement with these comments. As previously stated, the Commissioner is unaware of any evidence, nor has any been presented, that demonstrates that the improvement of the certification scheme and the im-

position of additional requirements on the sale and shipment of pet turtles would effectively solve the *Salmonella* and *Arizona* problem.

9. Ten comments suggested that the sale of pet turtles should be prohibited until the turtle industry has demonstrated its ability to produce *Salmonella*- and *Arizona*-free turtles.

The Commissioner agrees with these comments, and feels that the turtle industry, as well as all industry, has the responsibility for producing a hazard-free product. Therefore, the Commissioner concludes, for the reasons stated above, that a ban is the only effective means of controlling the problem.

10. Two comments, one of which was from a member of Congress, suggested a 1-year moratorium on the banning of turtles in order to give the turtle industry a further opportunity to produce uncontaminated turtles and an improved certification scheme.

The Commissioner concludes that the request for a 1-year moratorium must be denied because there is no factual basis for believing that *Salmonella*- and *Arizona*-free turtles can be produced or that an improved certification scheme could be developed within the 1-year period. Furthermore, a moratorium does not protect the public against the demonstrated hazards during that period.

The Commissioner wishes to make it clear, however, that this denial of a 1-year moratorium on the banning of turtles does not preclude the turtle industry from undertaking the development of an improved certification scheme or a *Salmonella*- and *Arizona*-free turtle. If in fact a significantly improved certification scheme is developed or a *Salmonella*- and *Arizona*-free turtle is produced by the turtle industry, the Commissioner, based on the data presented by interested persons, will consider changing the restrictions on the sale and distribution of turtles.

11. Thirteen comments expressed the opinion that an exception should be made for the turtle "fancier" and for any bona fide scientific, educational, or exhibitional purposes.

The regulation provides an exception for bona fide scientific, educational, and exhibitional purposes. The Commissioner concludes that this exception is reasonable and will not present a public health hazard since the scope of the exception is limited to a specific segment of society consisting of experts in the field who are fully aware of the contamination problems associated with turtles and the necessary precautions required to prevent such contamination. While turtle fanciers may be similarly competent to handle turtles safely, no comment has suggested, and the Commissioner has been unable to ascertain an enforceable exemption that would require a business to restrict its sales only to such qualified persons.

The proposed regulation has been revised to exempt sales not in connection with a business. This exemption will permit a hobbyist to make an occasional sale to another hobbyist, as long as such sales are not so frequent as to make the seller a dealer. In addition, the Commissioner will consider petitions to amend the prohibition to permit the sale of identified species, if it can be demonstrated that the species are so rare and expensive as to be of interest only to turtle hobbyists.

12. Six comments suggested an exception for adults so that anyone over the age of 18 could purchase pet turtles.

The Commissioner has previously addressed this issue in the order published in the FEDERAL REGISTER of November 18, 1972 (37 FR 24670). At that time, the Commissioner concluded that the greatest protection can be achieved by controlling the source of possible human infections. Many turtles are bought by adults and then taken home and given directly to children. Therefore, the Commissioner concludes that there can be no general exception for adults.

13. Three comments felt that interstate shipment of small turtles and viable turtle eggs should be banned but that intrastate shipment should be allowed.

The Commissioner concludes that the interstate spread of disease through *Salmonella*- and *Arizona*-contaminated turtles cannot be fully controlled without extending the ban to intrastate sales. All turtles present the same illness potential from *Salmonella* and *Arizona* organisms. Contaminated turtles may be purchased in one State for use as a pet in another. In addition, the existence of lawful business operations selling turtles within a State creates the possibility of unlawful interstate sales that are difficult or impossible to detect and stop. Therefore, The Commissioner finds that a prohibition on the sale of all turtles, regardless of origin or destination, is in his judgment necessary to prevent the spread of communicable diseases from one State to another.

The general prohibition on the sale of turtles does not apply to live turtles and viable turtle eggs intended for sale to foreign countries. The Commissioner believes that such shipments can be adequately controlled to prevent their diversion into domestic trade channels. The proposed regulation is revised to provide for this exception with the requirement that the outside of the shipping package be conspicuously labeled, "For Export Only." Export of items banned domestically under the condition that they are so marked is sanctioned by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) and the Consumer Product Safety Act (15 U.S.C. 2067). These statutory provisions represent congressional judgments that the diversion of export products into interstate commerce is unlikely when the products are properly labeled. The Commissioner concurs with this judgment for the present but will prohibit export sales as well if experience demonstrates that export turtles appear in interstate commerce.

Therefore, pursuant to provisions of the Public Health Service Act (sec. 361, 58 Stat. 703, as amended; 42 U.S.C. 264) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), Part 1240 of Title 21 of the Code of Federal Regulations is amended by revising § 1240.62 to read as follows:

§ 1240.62 Turtles.

(a) *Definition.* As used in this section the term "turtles" includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order Testudinata, class Reptilia, except marine species (families Dermachelidae and Chelonidae).

(b) *Sales; general prohibition.* Except as otherwise provided in this section, viable turtle eggs and live turtles with a carapace length of less than 4 inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution.

(c) *Destruction of turtles or turtle eggs; criminal penalties.* (1) Any viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial or public distribution shall be subject to destruction in a humane manner by or under the supervision of an officer or employee of the Food and Drug Administration in accordance with the following procedures:

(i) Any District Office of the Food and Drug Administration, upon detecting viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial or public distribution, shall serve upon the person in whose possession such turtles or turtle eggs are found a written demand that such turtles or turtle eggs be destroyed in a humane manner under the supervision of said District Office, within 10 working days from the date of promulgation of the demand. The demand shall recite with particularity the facts which justify the demand. After service of the demand, the person in possession of the turtles or turtle eggs shall not sell, distribute, or otherwise dispose of any of the turtles or turtle eggs except to destroy them under the supervision of the District Office, unless and until the Director of the Bureau of Foods withdraws the demand for destruction after an appeal pursuant to paragraph (c)(1)(ii) of this section.

(ii) The person on whom the demand for destruction is served may either comply with the demand or, within 10 working days from the date of its promulgation, appeal the demand for destruction to the Director of the Bureau of Foods, Food and Drug Administration. The demand for destruction may also be appealed within the same period of 10 working days by any other person having a pecuniary interest in such turtles or turtle eggs. In the event of such an appeal, the Bureau Director shall provide an opportunity for hearing by written notice to the appellant(s) specifying a time and place for the hearing, to be held within 14 days from the date of the notice but not within less than 7 days unless by agreement with the appellant(s).

(iii) Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The hearing shall be conducted by the Bureau Director or his designee, and a written summary of the proceedings shall be prepared by the person presiding. Any appellant shall have the right to hear and to question the evidence on which the demand for destruction is based, including the right to cross-examine witnesses, and he may present oral or written evidence in response to the demand.

(iv) If, based on the evidence presented at the hearing, the Bureau Director finds that the turtles or turtle eggs were held for sale or offered for any other type of commercial or public distribution in violation of this section, he shall affirm the demand that they be destroyed under the supervision of an officer or employee of the Food and Drug Administration; otherwise, the Bureau Director shall issue a written notice that the prior demand by the District Office is withdrawn. If the Bureau Director affirms the demand for destruction he shall order that the destruction be accomplished in a humane manner within 10 working days from the date of the promulgation of his decision. The Bureau Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the Bureau Director shall constitute final agency action, reviewable in the courts.

(v) If there is no appeal to the Director of the Bureau of Foods from the demand by the Food and Drug Administration District Office and the person in possession of the turtles or turtle eggs fails to destroy them within 10 working days, or if the demand is affirmed by the Director of the Bureau of Foods after an appeal and the person in possession of the turtles or turtle eggs fails to destroy them within 10 working days, the District Office shall designate an officer or employee to destroy the turtles or turtle eggs. It shall be unlawful to prevent or to attempt to prevent such destruction of turtles or turtle eggs by the officer or employee designated by the District Office. Such destruction will be stayed if so ordered by a court pursuant to an action for review in the courts as provided in paragraph (c)(1)(iv) of this section.

(2) Any person who violates any provision of this section, including but not limited to any person who sells, offers for sale, or offers for any other type of commercial or public distribution viable turtle eggs or live turtles with a carapace length of less than 4 inches, or who refuses to comply with a valid final demand for destruction of turtles or turtle eggs (either an unappealed demand by an FDA District Office or a demand which has been affirmed by the Director of the Bureau of Foods pursuant to appeal), or who fails to comply with the requirement in such a demand that the manner of destruction be humane, shall be subject to a fine of not more than $1,000 or imprisonment for not more than 1 year, or both, for each violation, in accordance with section 368 of the Public Health Service Act (42 U.S.C. 271).

(d) *Exceptions.* The provisions of this section are not applicable to:

(1) The sale, holding for sale, and distribution of live turtles and viable turtle eggs for bona fide scientific, educational, or exhibitional purposes, other than use as pets.

(2) The sale, holding for sale, and distribution of live turtles and viable turtle eggs not in connection with a business.

(3) The sale, holding for sale, and distribution of live turtles and viable turtle eggs intended for export only, provided that the outside of the shipping package is conspicuously labeled "For Export Only."

(4) Marine turtles excluded from this regulation under the provisions of paragraph (a) of this section and eggs of such turtles.

(e) *Petitions.* The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to amend this regulation. Any such petition shall include an adequate factual basis to support the petition, and will be published for comment if it contains reasonable grounds for the proposed regulation. A petition requesting such a regulation, which would amend this regulation, shall be submitted to the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

Effective date. This order shall become effective June 23, 1975.

(Sec. 361, 58 Stat. 703 as amended; 42 U.S.C. 264.)

Dated: May 19, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-13579 Filed 5-22-75;8:45 am]

Title 29—Labor

CHAPTER V—WAGE AND HOUR DIVISION, DEPARTMENT OF LABOR

PART 519—EMPLOYMENT OF FULL-TIME STUDENTS AT SUBMINIMUM WAGES

Fair Labor Standards; Correction

In FR Doc. 75–3798, beginning at 40 FR 6328 in the issue dated Tuesday, February 11, 1975, there were a number of typographical errors. Accordingly, FR Doc. 75–3798 is corrected as follows:

1. On page 6329, § 519.1(a) by changing "(36 FR 8755 and 39 FR 33841)" to (36 FR 8755) and by the Assistant Secretary for Employment Standards (39 FR 33841)".

2. On page 6330, § 519.5(b) by changing "employment opportunities" to "full-time employment opportunities".

3. On page 6331, § 519.6 (f), (g) and (h) by changing the colon following the first sentence in the paragraph to a period.

4. On page 6331, § 519.6 (f) and (j) and page 6333, § 519.16(e) by changing the format of these paragraphs to incorporate the parenthetical note as integral part of the paragraphs rather than a separate paragraph and by changing "Note.-" to "Note:".

5. On page 6332, § 519.7(b)(3) by deleting the second sentence and changing the first sentence to read as follows. "The employer operating any farm or retail or service establishment shall maintain records of the monthly hours of employment of full-time students at subminimum wages and of the total hours of employment during the month of all employees in the establishment except for those employed in agriculture who come within one of the other exemptions from the minimum wage provisions of the Act." This correction clarifies a procedure and imposes no changes in obligations on the public.

6. On page 6332, § 519.9(a) and page 6334, § 519.19(a) by changing "granted," on the sixth line to "granted" (i.e. the comma after the word "granted" is deleted.)

7. On page 6332, § 519.11(a) by changing "(36 FR 8755–6)" to "(36 FR 8755) and by the Assistant Secretary for Employment Standards (39 FR 33841)".

8. On page 6332, § 519.11(a) by changing "toh" in line 8 to "to".

9. On page 6332, § 519.12(a) by changing "fulltime" in lines 6 and 16 to "full-time".

10. On page 6332, § 519.13(a) by changing "Utah Area office" to "Utah Area Office".

11. On page 6333, § 519.16(e) on the eighth line, following "tion)" at the start of the line, by inserting a comma after "tion),".

12. On page 6334, § 519.17(b)(1) by changing "(b) (2), (3) and (4)" to "(b) (2) and (3)".

13. On page 6334, § 519.17(o) by changing the "(o)" to "(c)".

14. On page 6334, § 519.19(a) by changing the semi-colon ending line 10 to a colon.

Signed at Washington, D.C. this 16th day of May 1975.

WARREN D. LANDIS,
Acting Administrator,
Wage and Hour Division.

[FR Doc.75-13598 Filed 5-22-75;8:45 am]

Title 46—Shipping

CHAPTER II—MARITIME ADMINISTRATION, DEPARTMENT OF COMMERCE

SUBCHAPTER C—REGULATIONS AFFECTING SUBSIDIZED VESSELS AND OPERATORS

PART 294—OPERATING-DIFFERENTIAL SUBSIDY FOR BULK CARGO VESSELS ENGAGED IN CARRYING BULK RAW AND PROCESSED AGRICULTURAL COMMODITIES FROM THE UNITED STATES TO THE UNION OF SOVIET SOCIALIST REPUBLICS

Fixtures Made on and After April 1, 1975

Part 294 of Title 46, Code of Federal Regulations, which prescribes regulations governing the payment of operating-differential subsidy to operators of bulk cargo vessels engaged in carrying bulk raw and processed agricultural commod-