available to the Commission upon request, these exemption provisions fall within the Paperwork Reduction Act. 44 U.S.C. 3501 *et seq.* The Commission is prohibited from enforcing these provisions unless they have been "cleared" by the Office of Management and Budget. However, the Commission has decided that the entire exemption is unnecessary. Therefore, rather than requesting OMB clearance for the provision, the Commission is revoking the exemption.

B. Background

In December 1965 the Food and Drug Administration, the agency that then administered and enforced the FHSA (before its amendment in 1966, the Federal Hazardous Substances Labeling Act), issued the exemption for unlabeled containers described in *Introduction.* 30 FR 16200–01 (Dec. 29, 1965); 21 CFR 191.64. The preamble to this exemption stated (it its entirely).

> After consideration of inquiries and representatives received from regulated industry, and other relevant information, the Commissioner of Food and Drugs has concluded that within the conditions set forth below it is not necessary for the adequate protection of the public health and safety for a packing firm to label filled containers of household articles subject to the Federal Hazardous Substances Labeling Act prior to shipment to a distributor firm if such articles are properly labeled by the distributor firm prior to retail distribution.

In 1973, when the Commission took over administration and enforcement of the FHSA, it reissued this exemption provision, in essentially identical form. 38 FR 27012 (Sept. 27, 1973); 16 CFR 1500.84.

C. Proposed Revocation

On March 5, 1984 the Commission proposed to revoke the exemption (49 FR 8007), for the reasons discussed in section D below. The Commission did not receive any public comments on this proposal.

D. Discussion

When the Commission proposed to revoke the exemption provision of 16 CFR 1500.84, it had two reasons for believing that exemption to be unnecessary. In the absence of any public comments or other available information to the contrary, the Commission still believes the two reasons to be valid:

1. The Commission has no evidence that the exemption has ever been used. While unlabeled foods or drugs might well be packaged in one establishment and then shipped to another establishment for labeling, we do not believe that this is an industry practice for any hazardous substances that are regulated under the FHSA. Rather, the Commission's understanding is that all hazardous substances are labeled at the packaging establishment.

2. Even if a firm did ship a packaged hazardous substance to a different establishment for labeling, the Commission nevertheless believes that the exemption is unnecessary. The FHSA prohibits movement in interstate commerce of misbranded hazardous substances, and such substances—by definition—must be "* * * intended, or packaged in a form suitable, for use in the household or by children * * *" 15 U.S.C. 1261(p). If any unlabled hazardous substance were being shipped to an establishment for the purpose of being labeled, it would be unlikely to fall within this definition. In its unlabeled state, it would not be suitable for use in a household or by children. In addition, it would not be intended to be used by ultimate consumers because it is intended, rather, to be labeled first. In short, the Commission would not enforce the FHSA against any products that the exemption is designed to protect, and no exemption is necessary.

Aside from the substantive reasons for revocation of the exemption provision, there are two additional matters:

1. *Impact on small businesses.* The Regulatory Flexibility Act (RFA) requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis of the impact of any proposed rule on small entities, including small businesses. 5 U.S.C. 603. The RFA also provides that an agency is not required to prepare a regulatory flexibility analysis if the agency certifies that the rule, if issued on a final basis, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b).

In proposing the revocation, the Commission found that it would not, if issued on a final basis, affect any small entities because no business (including any small business) was acting within its provisions. No entities other than businesses would be affected. Therefore, the Commission certified that the revocation would not have a significant economic impact on a substantial number of small entities. 49 FR 8007.

2. *Environmental considerations.* The Commission found the proposed revocation to fall generally within the categories of Commission actions described in 16 CFR 1021.5(c) that have little or no potential for affecting the human environment. In addition, the Commission concluded that there were no significant effects associated with the proposal. For both reasons—which are true of the final revocation, as well—neither an environmental assessment nor an environmental impact statement is required.

Therefore, pursuant to provisions of the Administrative Procedure Act (5 U.S.C. 553) and the Federal Hazardous Substances Act (secs. 3(c), 10(a), 74 Stat. 374, 15 U.S.C. 1262, 1269, as amended), section 1500.84 of Title 16, Chapter II, Subchapter C of the Code of Federal Regulations is revoked, removed, and reserved.

Effective date: The revocation will be effective an September 14, 1984.

Authority: 5 U.S.C. 553; 15 U.S.C. 1262, 1269.

List of Subjects in 16 CFR Part 1500

Consumer protection, Labeling, Exemptions.

Dated: August 10, 1984.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 84–21740 Filed 8–14–84; 8:45 am]

BILLING CODE 6355–01–M

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16 CFR Part 1700

Amendment to Child-Resistant Packaging Requirements; Diphenhydramine Base

AGENCY: Consumer Product Safety Commission.

ACTION: Final amendment.

SUMMARY: In February 1984 the Commission issued a final regulation, under the Poison Prevention Packaging Act of 1970, to require child-resistant packaging for any preparation that contains more than 75 mg diphenhydramine hydrochloride in a single package and that is in a dosage form intended for oral administration. The Commission is now amending that regulation to broaden its scope, by requiring child-resistant packaging for preparations containing more than 66 mg diphenhydramine base in any oral dosage form.

DATE: The amendment will be effective on February 11, 1985.

FOR FURTHER INFORMATION CONTACT: Charles M. Jacobson, Division of Regulatory Management, Directorate for Compliance and Administrative Litigation, Consumer Product Safety Commission, Washington, D.C. 20207; (301) 492–6400.

SUPPLEMENTARY INFORMATION:

A. Background

The Poison Prevention Packaging Act of 1970 (the "PPPA"), 15 U.S.C. 1471–1476, authorizes the Commission to establish standards for the "special packaging" of any household substance if (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance and (2) the special packaging is technically feasible, practicable, and appropriate for such substance. Special packaging, also referred to as "child-resistant packaging," is defined as packaging that is (1) 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 (2) not difficult for normal adults to use properly. (It does not mean, however, packaging which all such children cannot open, or obtain a toxic or harmful amount from, within a reasonable time.) Under the PPPA, effectiveness standards have been established for special packaging (16 CFR 1700.15), as has a procedure for evaluating the effectiveness (§ 1700.20). Regulations have been issued requiring special packaging for a number of household products (§ 1700.14).

One category of products that is required to be in child-resistant packaging is any drug for human use that is in a dosage form intended for oral administration and that is required by federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug (16 CFR 1700.14(a)(10)). The Food and Drug Administration (FDA) determines whether a prescription shall be required for the dispensing of a particular drug. This determination involves factors including the potential toxicity of a drug. While the Commission similarly considers this toxicity factor in its special packaging determination, it also considers as a major factor the availability of a drug's package to young children.

When the FDA releases an oral drug from the prescription category, the drug is no longer required to be in child-resistant packaging by reason of being an oral prescription drug subject to § 1700.14(a)(10). Therefore, when the FDA takes such action, the Commission considers whether child-resistant packaging is nevertheless needed to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance.

The FDA recently released certain antihistamine drugs from the requirement that they be dispensed only by prescription, thereby allowing those drugs to be sold for over-the-counter (OTC) uses. [21] [1] One of these antihistamines is diphenhydramine hydrochloride, also referred to as diphenhydramine, which has been known to cause death and serious illness in children as the result of accidental overdose. Currently, the FDA has given final approval for the use of diphenhydramine in OTC antitussive (cough) preparations. [32] In addition, FDA's OTC Advisory Panel has recommended that the FDA release diphenhydramine for use in OTC sleep-aids. [33] In April 1982 the FDA announced an enforcement policy to permit the interm OTC marketing of such sleep-aids, pending a final agency determination on the Panel's recommendation. [33] The future use of diphenhydramine in other OTC products is thought to be likely. These uses include preparations for the relief of symptoms of rhinitis, common colds, and hay fever.

Following the FDA actions, the Commission proposed a rule, in July 1983, to require special packaging for any preparation that contains more than 75 mg diphenhydramine hydrochloride in a single package and in a dosage form intended for oral administration. 48 FR 31664 (July 11, 1983 [30] On February 15, 1984 the Commission published that special packaging rule in final form, to become effective on August 13, 1984. 49 FR 5737. 49 FR 5737 (Feb. 15, 1984) [34].

On the same day, the Commission proposed to amend that final special packaging rule for diphenhydramine hydrochloride. 49 FR 5768 (Feb. 15, 1984) [35] The proposal was to broaden the scope of the rule by applying it to preparations containing more than 66 mg. diphenhydramine base in any oral dosage form. The Commission received no public comments on this proposal, and has no new information concerning it. Therefore, the Commission believes that the proposed amendment should be issued in final form. The supporting reasons are the same ones that supported the proposal, and they are essentially restated in sections B, C, D, and E below.

The language of the final amendment has been changed slightly from that used in the proposal. The words "the equivalent of" have been added to clarify the requirement.

B. Toxic Effects of Diphenhydramine

The most commonly observed adversed effects associated with therapeutic use of antihistamines include drowsiness, dry mouth, and gastrointestinal complaints such as nausea, vomiting, and diarrhea. For adults, the most common signs of toxicity from overdosage of antihistamines appear to be the result of central nervous system depressive effects. [4, 6] If sufficiently high doses are taken, symptoms of drowsiness, dizziness, and loss of coordination can be followed by carido-respiratory depression and death.

By contrast, children appear to be more sensitive to the central nervous system stimulatory effects of antihistamines. The primary symptoms of overdosage in children are hallucinations, delirium, tremors, high fever, and convulsions. [4, 6] Terminally, a depressive phase ensues, leading to coma, cardio-respiratory collapse, and death. The major life-threatening consequences of overdosage in children have been effectively controlled in cases where the patient was able to obtain the proper treatment in a medical facility; however, rapid access to a medical facility is necessary. Normal first aid procedures may prove ineffective, since diphenhydramine can produce a strong antiemetic effect. [4]

C. Ingestion and Injury Data

Both the medical literature and the available ingestion data indicate a relatively low incidence of serious injury associated with accidental ingestion of OTC antihistamines by children under age five; however, some prescription antihistamines have caused serious injury and even death to young children. It is possible that the inherently lower toxicity of some of the OTC antihistamines, as well as their reduced dosage levels, accounts for the low incidence of injuries involving OTC antihistamines. Of the antihistamines that were previously prescription drugs but are now approved for certain OTC uses, diphenhydramine has caused a number of childhood injuries and deaths.

The Commission's staff reviewed medical literature for the years from 1950 to 1960 and noted 22 reports of serious symptoms caused by antihistamines overdose in children under five years of age; six of these cases resulted in death. Eighteen of the 22 cases appear to be due to accidental ingestion. Diphenhydramine was

[1] The numbers in brackets refer to the reference documents listed at the end of this notice.

involved in 16 of the 22 reported cases and in four of the six fatalities. [1, 2, 3, 5, 7, 8, 9, 10] In one reported case [7], a 13-month-old child suffered major motor seizures, serious cardiac arrhythmia, and cardio-respiratory depression following ingestion of 100–150 mg of diphenhydramine hydrochloride.

Data from the FDA's National Clearinghouse for Poison Control Centers for the years 1977 through 1980 show that a total of 632 accidental ingestions of diphenhydramine were reported during this four-year period. [14] Of these cases, 89 reported some symptomatology (i.e., lethargy, nausea, vomiting, etc.). A total of 20 children were hospitalized. Eight of the hospitalized children reported symptoms.

The Commission's death certificate file shows that seven deaths were reported for children under five years of age involving antihistamine preparations during the period of 1973 through 1980. [14, 23] Five of these deaths involved products containing diphenhydramine hydrochloride.

D. Need for Special Packaging

Preparations containing diphenhydramine in all oral dosage forms could result in injuries and poisonings among children, if they are not in special packaging. [27] The FDA is already permitting diphenhydramine monocitrate for over-the-counter use in sleep aids. Other forms of diphenhydramine may well be similarly permitted for OTC use in the future, as antitussives, sleep aids, or other products.

The regulation issued in final form in February 1984 applies only to diphenhydramine hydrochloride. [34] Therefore, the Commission believes that that regulation should be broadened to cover diphenhydramine base in all oral dosage forms. The Commission has determined that the equivalent of 75 mg diphenhydramine hydrochloride is 66 mg diphenhydramine base because 75 mg diphenhydramine hydrochloride consists of 66 mg diphenhydramine base and 9 mg hydrochloride. [26, 27] Based on the toxicity data that supported the diphenhydramine hydrochloride regulation, the amendment applies to all covered preparations containing that amount or more.

E. Technical Feasibility, Practicability, and Appropriateness

In issuing a standard for special packaging under the PPPA, the Commission is required by section 3(a)(2) of the PPPA, 15 U.S.C. 1472(a)(2), to find that the special packaging is "technically feasible, practicable, and appropriate . . . ."

1. *Technical feasibility.* Whether diphenhydramine preparations are marketed in tablet or liquid form, there are numerous package designs that meet the requirements of 16 CFR 1700.15(b) and that would be suitable for use with them. [12]

2. *Practicability.* Because many existing designs that could be used to market diphenhydramine preparations are currently being used with other drugs and dietary supplements, it is clear that special packaging for these products is practicable in that it is adaptable to modern mass production and assembly line techniques. The Commission would anticipate no major supply or procurement problems for packagers of diphenhydramine-containing products or the manufacturers of child-resistant closure and capping equipment. [12] In addition, the Commission would expect no serious problems experienced by manufacturers of the products in incorporating the child-resistant packaging features into their existing packaging lines. [12]

3. *Appropriateness.* As shown by the use of many existing suitable designs with other drug products, special packaging is appropriate since it is available in forms that are not detrimental to the integrity of the substance and that do not interfere with its storage or use. [12]

Accordingly, the Commission finds that special packaging for diphenhydramine-containing preparations is technically feasible, practicable, and appropriate.

F. Effective Date

The PPPA provides that, except for good cause, no regulation shall take effect sooner than 180 days or later than one year from the date such regulation is issued. The Commission decided to apply this range to the proposed amendment.

The Commission proposed an effective date of 180 days following final issuance, based on the belief that this would provide any manufacturers of diphenhydramine preparations with sufficient lead time to comply with the special packaging requirements. Since no public comments provided arguments or data to support a shorter or longer period of lead time, the Commission has decided that the final amendment will become effective in 180 days. This means that the original rule for diphenhydramine hydrochloride will become effective on August 13, 1984 and the amended rule for diphenhydramine base will become effective on February 11, 1985.

G. Environmental Considerations

Rules requiring poison prevention packaging of products normally have little or no potential for affecting the human environment, and, therefore, neither an environmental assessment nor an environmental impact statement is required. *See* 16 CFR 1021.5(c)(3). From the facts then available, the Commission concluded in February 1984 that the proposed amendment, if issued, would have no significant effects on the environment. The Commission continues to believe that there will be no such effects.

H. Regulatory Flexibility Act Certification

Using the criteria of the Regulatory Flexibility Act, 5 U.S.C. 601(3), the Commission staff concluded that no firm that might be required to institute changes to its packaging under the proposed amendment and no firm doing business with any directly affected firms would be subject to any significant effects as a result of the proposed amendment. Therefore, the Commission certified that the proposed amendment would not, if issued, have a significant economic impact on a substantial number of small entities.

The amendment will not apply to any preparations that are currently marketed, other than those that are already covered by the packaging requirement for diphenhydramine hydrochloride that was issued in February 1984. As discussed in sections A and D above, future marketing of diphenhydramine base products is likely. Even if any preparations will be required to be converted to special packaging by the final amendment, the costs will not be significant. As discussed in section E above, the Commission has found the amendment to be technically feasible, practicable, and appropriate.

I. Conclusion

Therefore, having considered the available human experience data and the medical literature, the Commission concludes that the requirement for special packaging set forth below should be issued. In making this determination, the Commission has considered—

(1) The reasonableness of the amendment;

(2) Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) The manufacturing practices of industries affected by the PPPA; and

(4) The nature and use of the diphenhydramine preparations covered by the amendment.

Accordingly, pursuant to provisions of the Poison Prevention Packaging Act of 1970 (Pub. L. 91–601, secs. 2(4), 3, 5, 84 Stat. 1670–72; 15 U.S.C. 1471(4), 1472, 1474) and under the authority vested in the Commission by the Consumer Product Safety Act (Pub. L. 92–573, sec. 30(a), 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission revises paragraph (a)(17) to 16 CFR 1700.14, to read as follows (although unchanged, the introductory text of paragraph (a) is included below for context):

§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and that the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(17) *Diphenhydramine.* Preparations for human use in a dosage form intended for oral administration and containing more than the equivalent of 66 mg diphenhydramine base in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), if packaged on or after February 11, 1985.

Authority: Pub. L. 91–601, secs. 2(4), 3, 5, 84 Stat. 1670–72; 15 U.S.C. 1471(4), 1472, 1474; Pub. L. 92–573, sec. 30(a), 86 Stat. 1231; 15 U.S.C. 2079(a).

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

Dated: August 9, 1984.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of References

1. Aaron, F. E. A case of acute diphenhydramine hydrochloride poisoning. British Med. J., 2:24, 1953.

2. Brody, J. I., Tobin, J. L. Apnea due to Benadryl. Ann. Intern. Med., 47:172–177, 1957.

3. Davis, J. H. and Homer, H. H. Accidental Benadryl Poisoning: Report of a Fatal Case, J. Pediatrics. 34:358–361, 1949.

4. Douglas, William W. Histamine and Antihistamines; 5-Hydroxytryptamine and Antagonists. In *the Pharmacological Basis of Therapeutics.* (Goodman, L. S., and Gilman, A., eds.) The Macmillan Co., Toronto, 1970, pp. 635–641.

5. Duerfeldt, T. H. Acute Benadryl Poisoning: Case Report. Northwest Medicine, 46:781–782, 1947.

6. Gosselin, R. E., Hodge, H. C., Smith, R. P., and Gleason, M. N. *Clinical Toxicology of Commercial Products.* The Williams and Wilkins Co., Baltimore, 1976, pp. 35–36.

7. Hestand, H. E. and Teske, D. W. Diphenhydramine Hydrochloride Intoxication. J. Pediatrics. 90:1017–1018, 1977.

8. Reichelderfer, T. E. et al. Treatment of acute Benadryl (diphenhydramine hydrochloride) intoxication with severe central nervous system changes and recovery. J. Pediatrics. 46:303–307, 1955.

9. Reyes-Jacang, A. and Wenzyl, J. F. Antihistamine toxicity in children. Clinical Pediatrics, 297–299, May 1969.

10. Wyngaarden, J. B. and Seevers, M. H. The toxic effects of antihistaminic drugs. J.A.M.A., 145:277–282, 1951.

11. Transmittal memo, with attached impact analysis of DPH regulation, from Elliott Foutes, dated March 30, 1983.

12. Memo on technical feasibility, practicability, and appropriateness of DPH regulation, from Charles Wilbur, dated October 27, 1982.

13. Memo on update on diphenhydramine ingestions, from Dorothy Drago, dated April 1, 1983.

14. Memo on summary of data discussed in previous memos (dated 2/24/82 and 7/30/82) on diphenhydramine, from Fred Marozzi, dated December 8, 1982.

15. Transmittal memo with attached briefing paper on proposed diphenhydramine regulation, from Virginia White, dated June 3, 1983.

16. Memo on proposed diphenhydramine regulation (RESTRICTED), from Harleigh Ewell, dated June 6, 1983.

17. Vote sheets on proposed diphenhydramine regulation, dated June 6, 1983.

18. Memo on use of diphenhydramine in OTC nighttime sleep aids (RESTRICTED), from Elliot Foutes, dated July 14, 1982.

19. Memo on diphenhydramine hydrochloride (RESTRICTED), from Evelyn Spiro, dated March 8, 1982.

20. Memo on recommended level for regulation of diphenhydramine, with attached chart, from Fred Marozzi, dated July 30, 1982.

21. Final rule on Marketing Status of Ingredients recommended for over-the-counter use. 47 FR 17738, April 23, 1982.

22. Memo on recommendation with respect to development of a PPPA regulation covering OTC antihistamine preparations (RESTRICTED), from Denise Orzech, dated February 24, 1982.

23. Transmittal memo on recommendations for special packaging requirements under PPPA for OTC antihistamines, with attached briefing package, from Virginia White, dated August 24, 1982.

24. Memo on draft **Federal Register** notice proposing CRC requirements for diphenhydramine, from Harleigh Ewell, dated April 1, 1983.

25. Memo on draft proposed PPPA requirement for diphenhydramine (effective date) (RESTRICTED), from Harleigh Ewell, dated June 23, 1983.

26. Ballot vote sheets on reconsideration of the effective date in proposal to require special packaging for diphenhydramine preparations (RESTRICTED), from Harleigh Ewell, dated June 23, 1983.

27. Memo on diphenhydramine regulation update, from Denise Orzech, dated August 16, 1983.

28. Memo on OTC products containing DPH, from Elliot Foutes, dated Dec. 1, 1983.

29. Public comment from Drug Enforcement Administration, dated Aug. 26, 1983.

30. Proposed requirements for Child-Resistant Packaging; Diphenhydramine Hydrochloride, **Federal Register** document, dated July 11, 1983.

31. Transmittal memo with attached briefing paper on final rule for special packaging of preparations containing diphenhydramine, from Virginia White, dated January 1984.

32. Letter from M.J. Finkel, FDA to Warner-Lambert Co.; NDA6–514OTC, vol. 04TTFM004TTFM; Documents Management Branch, FDA, 5600 Fishers Lane, Rockville, MD 20857.

33. **Federal Register** notice; Diphenhydramine: Marketing status as a nighttime sleep-aid drug product for over-the-counter human uses. 47 FR 17740, April 23, 1982.

34. **Federal Register** document: Requirements for Child-Resistant Packaging; Diphenhydramine Hydrocholoride. 49 FR 5737, Feb. 15, 1984.

35. **Federal Register** document: Proposed Amendment to Child-Resistant Packaging Requirements; Diphenhydramine Base. 49 FR 5768, Feb. 15, 1984.

[FR Doc. 84–21624 Filed 8–14–84; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 11 and 389

[Docket No. RM83–13–000]

Annual Charges for Use of Government Dams and Other Structures Under Part I of the Federal Power Act

Issued: August 9, 1984.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule; notice of effective date and OMB control number.

SUMMARY: On May 24, 1984, the Federal Energy Regulatory Commission issued a final rule in Docket No. RM83–13–000, 49 Fed. Reg. 22770 (June 1, 1984) setting annual charges under section 10(e) of the Federal Power Act for hydroelectric projects which use Government dams or other structures. This notice sets forth

the OMB control number for the information collection requirements in this rule and the effective date of the rule.

EFFECTIVE DATE: August 15, 1984.

FOR FURTHER INFORMATION CONTACT: Jan Macpherson, Rulemaking and Legislative Analysis Division, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, (202) 357–8033.

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act, 44 U.S.C. 3501–3520 (1982) and the Office of Management and Budget's (OMB) regulations, 5 CFR Part 1320 (1983), require that OMB approve certain information collection requirements imposed by agency rule. On July 18, 1984, OMB approved the information collection requirements in 18 CFR 11.22(c) and 11.23(b) and issued Control Number 1902–0136 for these sections. Therefore, the final rule in Docket No. RM83–13–000 will become effective August 15, 1984.

Accordingly, Part 389, Chapter I, Title 18, Code of Federal Regulations is amended as set forth below.

1. The authority citation for Part 389 continues to read as follows:

Authority: Paperwork Reduction Act of 1980, 44 U.S.C. 3501–3520 (1982).

§ 389.101 [Amended]

2. The Table of OMB Control Numbers in § 389.101(b) is amended by inserting "11.22(c)" and "11.23(b)" in numerical order in the section column, and "0136" in the corresponding positions in the OMB Control Number column.

Kenneth F. Plumb,

Secretary.

[FR Doc. 84–21585 Filed 8–14–84; 8:45 am]

BILLING CODE 6717–01–M

INTERNATIONAL TRADE COMMISSION

19 CFR Parts 201, 204, and 207

Amendments to Rules of Practice and Procedure

AGENCY: International Trade Commission.

ACTION: Amendment of rules; final action.

SUMMARY: These rules amend Parts 201, 204, and 207 of the Commission's *Rules of Practice and Procedure*. Part 201 sets forth rules of general application; Part 204 governs Commission investigations concerning the effect of imports on agricultural programs (section 22 of the Agricultural Adjustment Act); and Part 207 governs investigations of whether injury to domestic industries results from imports sold at less than fair value or from subsidized exports to the United States.

The amendments to Part 201 provide, in particular, for an expansion of the definition of confidential business information to include certain additional information of commerical value; clearer marking of the confidential portions of documents for which confidential treatment is requested; certain changes concerning paper size of documents, unbound copies, and one-sided copying; clarification of the provision permitting additional time for responses when service is by mail; and adjustment of the fees charged for copying and searching for documents in response to requests under the Freedom of Information Act. The amendment to Part 204 deletes the word "Tariff" to reflect the change in name of the Commission in 1975 from the Tariff Commission. The amendments to Part 207 provide that the Commission will not serve on all parties to antidumping and countervailing duty proceedings responses to requests for confidential treatment or documents under protective order; conform the requirement concerning number of copies to be filed to that of Part 201; and reflect the change in name of the U.S. Customs Court to the U.S. Court of International Trade.

EFFECTIVE DATE: August 15, 1984.

FOR FURTHER INFORMATION CONTACT: William W. Gearhart, Esq., Assistant General Counsel, U.S. International Trade Commission, 701 E Street, NW., Washington, D.C. 20436, telephone 202–523–0487.

SUPPLEMENTARY INFORMATION: Section 335 of the Tariff Act of 1930 (19 U.S.C. 1335) authorizes the Commission to adopt such reasonable procedures and rules and regulations as it deems necessary to carry out its functions and duties.

Notice of these proposed changes was published in the **Federal Register** of April 12, 1984 (49 FR 14502). Persons wishing to comment on the proposed changes were given until May 12, 1984, to do so. Comments were received only from two parties, the law firm of Squire, Sanders & Dempsey, Washington, D.C., and the U.S. Steel Corp., Pittsburgh, Pa. Both parties recommended that the proposed addition to rule § 201.6(a) of the phrase "other information of commercial value" be deleted or that the term be narrowly construed. In addition, U.S. Steel opposed the amendment to rule § 207.3 providing that the Commission need no longer serve on all parties responses to requests for confidential treatment and responses to requests for confidential information in antidumping and countervailing duty cases. Their comments are available for public inspection in the Office of the Secretary to the Commission in the U.S. International Trade Commission Building, 701 E Street NW., Washington, D.C. 20436.

The Commission carefully considered comments submitted by both parties, but has decided that the rules as originally proposed should be adopted. The Commission does not believe that the proposed change in rule 201.6(a) is excessively broad or is likely to become a device relied upon by parties submitting data for shielding their submissions from public scrutiny. The Commission does not intend that the amendment become a basis for providing confidential treatment for briefs, letters, and other documents provided by parties which, while prepared at considerable expense and technically copyrightable, contain the basic facts and argumentation in support of their case. Rather, the Commission seeks to protect only a limited class of material: (1) Which is of commercial value, such as copyrighted material analyzing an industry sector which is sold commercially in the marketplace (e.g., Dunn and Bradstreet reports), and (2) which is deemed necessary to the Commission's investigation and which the Commission might otherwise have to purchase. The Commission is seeking to distinguish between material prepared by or for a party to be used in support of or in conjunction with their case, which would not be protectable on commercial value grounds, and material prepared for commercial sale to subscribers. In most cases, the Commission will be seeking to protect the preparer of the material rather than the submitter, such as where public access to the material or reproduction at 10 cents per page is likely to injure the preparer financially. Briefs prepared by lawyers and economic analyses prepared by economic consultants retained by the parties in the course of a proceeding would not qualify as "information of commercial value" necessary to the Commission's investigation which the Commission might otherwise have to purchase, even though such documents were prepared at considerable expense and are copyrightable.

The Commission also rejected U.S. Steel's request that rule 207.3 covering service of documents in antidumping and countervailing duty cases continue to require that the Commission serve copies on all parties of responses to

requests for confidential treatment from individual parties and responses to requests for access to confidential information under protective order. U.S. Steel opposed the change on the grounds that (1) parties submitting the request often did not properly serve other parties and that the Commission's service of a response was often the first notice which other parties received, and (2) other parties needed notice of the Commission response in order to determine that nature of the Commission's action and whether to object to it. The Commission proposed eliminating serving such responses on parties other than the requesting party because the serving of responses has become burdensome and the overwhelming number of requests for confidential treatment or access to confidential information are of a routine nature and of little interest to other parties. Copies of Commission responses to such requests are available and will continue to be available for public inspection in the Commission's public inspection file. In addition, requests for confidential treatment or confidential documents not containing a proper service list are not processed by the Commission until a proper service list is submitted, and rule § 207.3 provides that parties failing to properly serve other parties risk loss of their status as parties.

The amendments set forth below are intended to remedy problems that have arisen under existing Commission practice, reflect present costs incurred in furnishing information under the Freedom of Information Act, and correct certain errors in the Commission's rules.

Rule 201.6(a) is amended to include within the definition of confidential business information, in addition to information which concerns or relates to trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, "other information of commercial value," the disclosure of which is likely to have the effect of either (1) Impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions, or (2) causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information. Such "other information of commercial value" may include copyrighted material or other material of commercial value prepared or purchased at considerable expense by the submitter but which is not otherwise covered by the definition.

Rule 201.6(b)(3) is amended to require that persons requesting confidential treatment for documents containing business information clearly indicate on the cover of such documents the pages on which confidential information appears and identify the confidential information on those pages by means of brackets. Confidential versions of briefs and other documents presently filed with the Commission often do not clearly identify which information is confidential. When the Confidential information is not clearly identified, the Commission staff must spend extra time comparing confidential and nonconfidential versions in order to identify the confidential information. This causes delays in processing requests and may result in the Commission's inadvertent overlooking of portions not clearly marked as confidential.

Rule 201.6(b)(3) also is amended to refer to the requirement set forth in rule 201.8(d) that a nonconfidential version of confidential documents be furnished. Persons filing confidential documents often fail to file nonconfidential versions because they have failed to follow rule 201.8(d). This amendment would remind them of the rule 201.8(d) requirement.

Rule 201.8(d) is amended to require that all submissions be on letter-sized paper (8½ inches by 11 inches), except patent file wrappers or other documents prepared by or for another agency or court; and that the original and at least one copy of all submissions be printed on one side only and be unbound. These requirements will facilitate storage and reproduction of documents. The paper-size requirement was erroneously deleted from this rule in a previous revision.

Rule 201.16(d) is amended to make clear the fact that the additional time for responses permitted when service is by mail is 3 calendar days in the case of service to a person located in the United States and 10 calendar days in the case of a person located in a foreign country, rather than 3 or 10 working days.

Rule 201.20(a) is amended to provide that fees for search time for records will be computed at the rate of $8.00 per hour for time spent by agency personnel in grades GS–2 through GS–10 and at the rate of $16 per hour for time spent by agency personnel in grades GS–11 and above. This charge reflects the current level of Federal salaries. However, no charge will be imposed when the total charge for search time and copying does not exceed $25.00. On charges of $25.00 or less, the cost of billing, bookkeeping, and check processing tends to equal or exceed the fee collected. The Commission presently does not impose a fee for search time when the search time is one half hour or less.

Rule 201.20(b), which provides for copying fees, is amended to provide that the Commission will not impose a fee unless the total charge for search time and copying exceeds $25.00. The Commission presently does not impose a fee for copying unless the total charge for copying exceeds 50 cents.

Rule 201.20(c) is amended to provide that the Commission will not process a request for information which is expected to involve assessed fees in excess of $25.00 unless the request states that whatever cost is involved is acceptable or is acceptable up to a specified limit which covers anticipated costs. The present rule provides a limit of $15.00, but this limit has been rendered obsolete by rules 201.20 (a) and (b), which waive all search time and copying charges of $25.00 or less.

Rule 204.5 is amended to delete the word "Tariff" in Tariff Commission, the former name of this Commission. Due to an oversight, this reference was not deleted in earlier rule changes. The name of the agency was changed effective January 3, 1975, by section 171 of the Trade Act of 1974 (19 U.S.C. 2231).

Rule 207.3 is amended to provide that the Commission, in antidumping and countervailing duty proceedings, need not serve on all parties of record its responses to requests for confidential treatment from individual parties. It also is amended to make clear that the Commission will not serve on all parties responses to requests for access to confidential information under protective order.

Rule 207.45(b) is amended to provide that parties filing requests for a review of antidumping and countervailing duty actions must file an original and 14 copies of such documents (rather than 19 copies, as under the present rule). This change would conform this requirement to the copies requirement of rule 201.8(d).

Rules 207.50 and 207.51 are amended to reflect the fact that persons entitled to judicial review may seek such review in the U.S. Court of International Trade (rather than the U.S. Customs Court, the former name of this court).

List of Subjects

19 CFR Part 201

Administrative practice and procedure, Business and industry, Imports, Investigations.

19 CFR Part 204

Administrative practice and procedure, Agricultural commodities, Imports, Investigations.

19 CFR Part 207

Administrative practice and procedure, Antidumping, Business and industry, Countervailing duties, Investigations.

PART 201—[AMENDED]

Parts 201, 204, and 207 are amended as set forth below:

1. Paragraphs (a) and (b)(3) of § 201.6, which concerns confidential business information, are revised as follows:

§ 201.6 Confidential business information.

(a) *Definition.* Confidential business information is information which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either (1) impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions, or (2) causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information.

(b) * * *

(3) With each submission of, or offer to submit, business information which a submitter desires to be treated as confidential under paragraph (a)(2) of this section, the submitter shall provide the following, which may be disclosed to the public:

(i) A written description of the nature of the subject information;

(ii) A justification for the request for its confidential treatment;

(iii) A certification in writing under oath that substantially identical information is not available to the public;

(iv) A copy of the document (A) clearly marked on its cover as to the pages on which confidential information can be found, and (B) with information for which confidential treatment is requested clearly identified by means of brackets (except when submission of such document is withheld in accord with paragraph (b)(4) of this section); and

(v) A nonconfidential copy of the documents as required by § 201.8(d).

* * * * *

2. Paragraph (d) of § 201.8, which concerns filing of documents, is revised as follows:

§ 201.8 Filing of documents

* * * * *

(d) *Number of copies.* A signed original (or a copy designated as an original) and fourteen (14) copies of each document shall be filed. All submissions shall be on letter-size paper (8½ inches by 11 inches), except copies of documents prepared for another agency or a court (e.g., patent file wrappers or pleading papers). The original and at least one copy of all submissions shall be printed on one side only and shall be unbound (although they may be stapled or held together by means of a clip). In the event that confidential treatment of the document is requested under § 201.6, at least one additional copy shall be filed, in which the confidential business information shall have been deleted and which shall have been marked conspicuously "nonconfidential" or "public inspection." The name of the person signing the original shall be typewritten or otherwise reproduced on each copy.

* * * * *

3. Paragraph (d) of § 201.16, which concerns service of process and other documents, is revised as follows:

§ 201.16 Service of process and other documents.

* * * * *

(d) *Additional time after service by mail.* Whenever a party or Federal agency or department has the right or is required to perform some act or take some action within a prescribed period after the service of a document upon it and the document is served upon it by mail, three (3) calendar days shall be added to the prescribed period, except that when mailing is to a person located in a foreign country, ten (10) calendar days shall be added to the prescribed period.

4. Paragraphs (a)(1), (b), and (c) of § 201.20, which concerns fees for searching for or copying of records, are revised as follows:

§ 201.20 Fees.

(a) *Search for records.* (1) The charge will be computed at the rate of $8.00 per hour for actual search time spent by agency personnel in salary grades GS–2 through GS–10 and at the rate of $16.00 per hour for actual search time by agency personnel in salary grades GS–11 and above, with said charges to be computed in quarter hour increments; however, no charge will be imposed when the total charge for search time and copying of records (see § 201.20(b)) does not exceed $25.00.

* * * * *

(b) *Copying of records.* The charge for reproduction, duplication, or copying of records by the Commission will be 10 cents per page; however, no charge will be imposed when the total charge for search time (see § 201.20(a)) and reproduction, duplication, or copying of records does not exceed $25.00.

(c) Unless a request for information specifically states that whatever cost is involved is acceptable, or acceptable up to a specified limit that covers anticipated costs, a request that is expected to involve assessed fees in excess of $25.00 or the specified limit will not be deemed to have been received until the requester is advised of the anticipated costs and agrees to bear such costs.

* * * * *

5. Section 204.5, which concerns reports issued by the Commission as a result of investigations conducted under section 22 of the Agricultural Adjustment Act (7 U.S.C. 624), is revised as follows:

§ 204.5 Reports.

After completion of its investigation, the Commission will transmit to the President a report of the results thereof, including its findings and recommendations based thereon, and a statement of the steps taken in the investigation, together with a transcript of the evidence submitted at the hearing. A copy of such report will be transmitted to the Secretary of Agriculture.

6. Section 207.3, which concerns service of documents in connection with Commission proceedings under section 303, section 516A, and title VII of the Tariff Act of 1930 (19 U.S.C. 1303, 1516A, and 1671–1677) and sections 102–107 of the Trade Agreements Act of 1979 (Pub. L. 96–39, 93 Stat. 144), is revised as follows:

§ 207.3 Service of documents.

Any party submitting a document for inclusion in the record of the investigation shall, in addition to complying with § 201.8, serve a copy of each such document on all other parties to the investigation in the manner prescribed in § 201.16. Failure to comply

with the requirements of this rule may result in removal from status as a party. The Commission shall make available to all parties to the investigation a copy of each document, except transcripts of conferences and hearings and responses to requests under § 201.6(b) (confidential business information) and § 201.76 (documents under protective order), placed in the record of the investigation by the Commission.

7. Paragraph (b)(1)(i) of § 207.45, which concerns investigations to review certain antidumping and countervailing duty actions, is revised as follows:

§ 207.45 Investigation to review outstanding determination.

* * * * *

(b) *Procedures*—(1) *Commencement of proceedings*—(i) *Upon receipt of a request.* A proceeding is commenced upon the filing with the Commission of the original and fourteen (14) true copies of a request. Requests for a review investigation may be filed by any person. All requests shall set forth a description of changed circumstances sufficient to warrant the institution of a review investigation by the Commission under this section.

* * * * *

8. Paragraphs (a) and (b) of § 207.50, which concerns judicial review under section 516A of the Tariff Act of 1930 with respect to antidumping and countervailing duty actions, is revised as follows:

§ 207.50 Judicial review.

(a) *In general.* Persons entitled to judicial review under section 516A of the Act may seek review in the U.S. Court of International Trade.

(b) *Transmittal of record.* In the event a Commission determination is appealed to the U.S. Court of International Trade under section 516A, a copy of the record in the proceeding before the Commission, as such record is defined in § 207.2(j), or a certified list of all items therein, will be transmitted to the court by the Secretary in accordance with the rules of the court.

* * * * *

9. Paragraph (a) of § 207.51, which concerns judicial review of the denial of applications for disclosure of certain confidential information under protective order, is revised as follows:

§ 207.51 Judicial review of denial of application for disclosure of certain confidential information under protective order.

(a) *In general.* Persons entitled to judicial review under section 777(c)(2) of a Commission determination not to disclose confidential information concerning domestic price or cost of production may apply to the U.S. Court of International Trade for an order directing the Commission to make the information involved available.

* * * * *

Issued: August 9, 1984.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 84-21719 Filed 8-14-84; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 16

Statement of Policy as to Administrative Action To Be Taken by the Federal Highway Administration in Instances of Irregularities; Rescission of Regulation

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Rescission of regulation.

SUMMARY: This document rescinds the FHWA regulation on debarment procedures because the regulation has been superseded by a Department of Transportation regulation which prescribes uniform formal procedures for the suspension and debarment of participants in DOT financial assistance programs if serious misconduct or improper use of Federal financial assistance funds is involved.

EFFECTIVE DATE: May 18, 1984.

FOR FURTHER INFORMATION CONTACT: Mr. Hugh T. O'Reilly, Office of the Chief Counsel, (202) 426-0780, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

SUPPLEMENTARY INFORMATION: The regulations contained in 23 CFR Part 16 were published to prescribe the administrative action which should be taken by the Administrator in order to safeguard the Federal interest in instances of irregularities in the administration and execution of the direct Federal and Federal-aid highway programs. On April 18, 1984, a final rule was published in the **Federal Register** (49 FR 15197) by the Office of the Secretary of Transportation which sets forth procedures that would enable the DOT, including the FHWA to deny any individual, corporation, or other business entity the opportunity to participate in a program of a recipient receiving DOT financial assistance, including contracts awarded pursuant to grants, because of serious misconduct or improper use of Federal financial assistance. Since the DOT regulations adequately safeguard the FHWA interest in instances where government funds are not properly utilized, Part 16 is no longer necessary and is, therefore, rescinded. However, any unacceptability actions pending under the procedures of 23 CFR Part 16 on the date of this rescission shall not abate.

The FHWA has determined that this document contains neither a major rule under Executive Order 12291 nor a significant regulation under the regulatory policies and procedures of the Department of Transportation. The economic impact of this final rule has been found to be so minimal that further evaluation is unnecessary. Since the impact of this final rule is expected to be minimal, the agency certifies that it will not have a significant economic impact on a substantial number of small entities.

Since this is a technical amendment that merely rescinds FHWA provisions which have been superseded by DOT provisions which are more formal and uniform, public comment is unnecessary. For this reason, the FHWA finds good cause to make the amendment final without prior notice and opportunity for comment and without a 30-day delay in effective date under the Administrative Procedure Act. For the same reason, notice and opportunity for comment are not required under the regulatory policies and procedures of the Department of Transportation because it is not anticipated that such action would result in the receipt of useful information.

PART 16—STATEMENT OF POLICY AS TO ADMINISTRATIVE ACTION TO BE TAKEN BY THE FEDERAL HIGHWAY ADMINISTRATION IN INSTANCES OF IRREGULARITIES [REMOVED]

In consideration of the foregoing, the FHWA hereby removes Part 16 "Statement Of Policy As To Administrative Action To Be Taken By The Federal Highway Administration In Instances Of Irregularities" from title 23, Code of Federal Regulations. Existing periods of unacceptability and pending actions of unacceptability do not abate by reasons of this action.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The procedures provided by OMB Circular A-95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects apply to this program)

(23 U.S.C. 315; 49 1.48(b))