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By the Commission.

Dated: October 2, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–25815 Filed 10–4–96; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 355

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment; Partial Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment; partial delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) anticaries drug products (products that aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded (60 FR 52478, October 6, 1995). This final rule makes a nonsubstantive change in the definition of a dentifrice, clarifies how OTC dentifrice gels are included in certain labeling aspects of the final monograph, and clarifies that the second general warning regarding "accidental ingestion" is the statement to be used for OTC fluoride-containing dentifrice, treatment rinse, and preventive treatment gel drug products. This amendment also revises the second general warning statement to indicate to consumers that "accidental ingestion" of these products means swallowing more than is used during normal brushing or rinsing. Because of the need to revise labeling for this minor revision, the agency is delaying the effective date of the regulation to provide manufacturers with an additional 6 months to comply with the labeling requirements of the monograph. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: The effective date for § 355.50 added at 60 FR 52508, October 6, 1995, is delayed until April 7, 1997. This final rule is effective April 7, 1997.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 6, 1995 (60 FR 52478), FDA issued a final monograph for OTC anticaries drug products (21 CFR part 355) establishing conditions under which the drug products that are subject to that monograph will be generally recognized as safe and effective and not misbranded. The effective date of the monograph is October 7, 1996.

On April 17, 1996, the Joint Oral Care Task Group of the Nonprescription Drug Manufacturers Association (NDMA) and the Cosmetic, Toiletry and Fragrance Association (CTFA) (the Task Group) submitted three citizen petitions (Refs. 1, 2, and 3) to amend the final monograph for OTC anticaries drug products. The first petition requested a technical amendment to the final monograph to clarify the use of the term "gel" in the context of dentifrice gels and preventive treatment gels in § 355.50(c) and (d). The petition indicated that this technical amendment would be helpful in avoiding unnecessary discussion and/or confusion about how OTC dentifrice gels are included in certain labeling aspects of the final monograph.

The two other petitions requested an exemption from the requirements of the general warnings under § 330.1(g) (21 CFR 330.1(g)) for OTC fluoride-containing dentifrice, treatment rinse, and preventive treatment gel drug products based on these products' long history of safe use, the package size limitations to limit potential toxicity, and the potential for consumer confusion and alarm that the general warnings would cause.

The Task Group added that the second general warning for these drug products is confusing with regard to the terms "accidental overdose" and "accidental ingestion." Because these products are not intended for oral administration in the context of an orally administered medicine and because no dosage amounts are specified in the labeling, there is no "overdose" per se. The Task Group contended that consumers may mistakenly consider any accidental ingestion (even the swallowing of some product during normal usage) as dangerous and thus needlessly call health professionals in poison control centers, emergency rooms, and doctors' offices for assistance.

II. The Agency's Response to the Petitions

Based on these petitions, the agency has determined that in order to avoid possible confusion about how OTC dentifrice gels and powders are included in certain labeling aspects of the final monograph for OTC anticaries drug products, the definition of "Dentifrice" in § 355.3(e) should be revised to read: "An abrasive-containing dosage form (gel, paste, or powder) for delivering an anticaries drug to the teeth."

To clarify how OTC dentifrice gels are included in the labeling aspects in § 355.10(a)(1), (b)(1), (b)(2), and (c)(1) and § 355.50(d)(1)(i) and (d)(1)(ii) of the final monograph, this technical amendment revises the heading in each of these sections by adding the words "gel or" before the word "paste." To better clarify how OTC dentifrice gels and preventive treatment gels are included in the labeling aspects in § 355.50(c)(1) and (c)(2), respectively, this technical amendment includes the following revisions: (1) The heading in § 355.50(c)(1) is revised to read: *"For all fluoride dentifrice (gel, paste, and powder) products,"* and (2) the heading in § 355.50(c)(2) is revised to read: *"For all fluoride rinse and preventive treatment gel products."*

With regard to the second general warning in § 330.1(g), the agency points out that the correct second general warning to be used for fluoride-containing gel, paste, powder, treatment rinse, and preventive treatment gel drug products included in the final monograph is the statement for accidental ingestion and not for accidental overdose. That statement reads: "In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately." The agency considers this information important to provide consumers guidance if an accidental ingestion occurs, particularly if a young child accidentally swallows or ingests an

excessive amount of an OTC anticaries drug product.

However, the agency recognizes that this statement may be confusing to consumers who might think that any accidental ingestion of an OTC anticaries drug product during normal use may be dangerous. Therefore, to clarify to consumers that "accidental ingestion" does not refer to the amount of product swallowed during normal use, but refers to excessive ingestion of the drug product, this technical amendment revises the second general warning in § 355.50(c)(1) and (c)(2) of the final monograph to read as follows: "If you accidentally swallow more than used for" (select appropriate word: "brushing" or "rinsing"), "seek professional assistance or contact a Poison Control Center immediately." The agency considers these labeling revisions as minor clarifying changes that do not change the substance of the labeling requirements contained in the final rule.

In a communication with the petitioner (Ref. 4), the agency indicated that it had not decided on the exact revised wording of the second general warning and asked the petitioner to make a suggestion. The petitioner subsequently suggested (Ref. 5) the following language: "If an amount larger than used for [brushing] is swallowed, call a Poison Control Center or doctor right away." The agency considered the first part of the petitioner's suggestion in developing the language that appears in this final rule. However, the agency is not changing the wording of the second part of this statement at this time because such a change would be more than a technical amendment, which would constitute a need for notice and comment rulemaking.

In a future issue of the **Federal Register**, the agency intends to propose a revision to the general warnings labeling in § 330.1(g). This revision will include changes in the language of the second part of this warning statement. The agency will provide an opportunity for full public comment before establishing the revised wording and will further consider the comment's suggestion at that time. The agency does not want to implement revised labeling for that part of the warning for only anticaries drug products at this time, but will implement revised labeling for all OTC drug products uniformly at a later date.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). This final rule institutes changes that are nonsubstantive in nature. Because the revisions are not controversial and because, when effective, they provide clarification of the final monograph for OTC anticaries drug products, FDA finds that the notice and comment procedures are unnecessary and not in the public interest (5 U.S.C 553 (b) and (d)). The agency believes that delaying the effective date for 6 months will provide sufficient time for industry to implement fully the labeling revisions included in this technical amendment.

III. References

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

(1) Comment No. CP6 (Vol. 22), Docket No. 80N–0042, Dockets Management Branch.

(2) Comment No. CP6 (Vol. 24), Docket No. 80N–0042, Dockets Management Branch.

(3) Comment No. CP6 (Vol. 26), Docket No. 80N–0042, Dockets Management Branch.

(4) Letter from D. Bowen, FDA, to R. W. Soller, Nonprescription Drug Manufacturers Association, coded as LET32, Docket No. 80N–0042, Dockets Management Branch.

(5) Letter from R. W. Soller, Nonprescription Drug Manufacturers Association, to D. Bowen, FDA, dated July 11, 1996, Docket No. 80N–0042, Dockets Management Branch.

IV. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic environmental, public health and safety, and other advantages: distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The agency therefore concludes that none of these technical changes included in this final rule is a major rule. In addition, this final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule makes a minor revision in some labeling that was to become effective on October 7, 1996, but which will not be required now until April 7, 1997. Thus, this final rule will not impose a significant economic burden on affected entities. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Rather, the labeling statements are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 355

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 355 is amended as follows:

PART 355—ANTICARIES DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 355 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 355.3 is amended by revising paragraph (e) to read as follows:

§ 355.3 Definitions.

* * * * *

(e) *Dentifrice.* An abrasive-containing dosage form (gel, paste, or powder) for delivering an anticaries drug to the teeth.

* * * * *

§ 355.10 [Amended]

3. Section 355.10 is amended in the headings for paragraphs (a)(1), (b)(1), (b)(2), and (c)(1) by adding the words "gel or" before the word "paste".

4. Section 355.50 is amended by revising paragraphs (c)(1) and (c)(2), and in the headings for paragraphs (d)(1)(i) and (d)(1)(ii) by removing the word "Paste" and adding in its place the words "Gel or paste" to read as follows:

§ 355.50 Labeling of anticaries drug products.

* * * * *

(c) * * *

(1) *For all fluoride dentifrice (gel, paste, and powder) products.* "Keep out of the reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately." These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

(2) *For all fluoride rinse and preventive treatment gel products.* "Keep this and all drugs out of the reach of children. If you accidentally swallow more than used for" (select appropriate word: "brushing" or "rinsing"), "seek professional assistance or contact a Poison Control Center immediately." These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

* * * * *

Dated: September 30, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–25599 Filed 10–4–96; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310, 1313

[DEA NUMBER 138P]

RIN 1117–AA32

Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule; withdrawal.

SUMMARY: DEA is withdrawing its rulemaking regarding Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act) which was published in the **Federal Register** on August 7, 1996 (61 FR 40981). The final rule has been superseded by the Comprehensive Methamphetamine Control Act of 1996, which declares the final rule null and void and of no effect.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC. 20537, Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: DEA published a notice of proposed rulemaking (NPRM) regarding Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act) in the Federal Register on October 31, 1995 (60 FR 55348). The NPRM proposed certain amendments to Title 21, Code of Federal Regulations (CFR), Parts 1309, 1310, and 1313, and was open for public comment until January 2, 1996. Following the comment period, DEA published a final rulemaking on August 7, 1996 (61 FR 40981), which was to become effective on October 7, 1996. However, on September 29, 1996, Congress passed the Comprehensive Methamphetamine Control Act of 1996, which provides that "The final rule concerning removal of exemption for certain pseudoephedrine products marketed under the Federal Food, Drug, and Cosmetic Act published in the Federal Register of August 7, 1996 (61 FR 40981–40933) is null and void and of no force or effect." As a result, the amendments contained in the final rule are canceled and the regulatory text of 21 CFR Parts 1309, 1310, and 1313 remains unchanged.

Accordingly, DEA's rulemaking entitled Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act), published in the Federal Register as a proposed rule on October 31, 1995 (60 FR 55348) and as a final rule on August 7, 1996 (61 FR 40981), is withdrawn.

Dated: October 2, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 96–25665 Filed 10–4–96; 8:45 am]

BILLING CODE 4410–09–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[OPPTS–50617A; FRL 5396–6]

RIN 2070–AA58

Benzidine-Based Chemical Substances; Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a) of the Toxic Substances Control Act (TSCA) which requires persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of certain benzidine-based chemical substances for any significant new use as described in this rule. EPA believes that this action is necessary because benzidine-based chemical substances may be hazardous to human health and that the uses governed by this rule may result in significant exposure to workers handling those substances. The required notice provides EPA with the opportunity to evaluate any intended new uses and associated activities before the benzidine-based chemical substances can be introduced into the marketplace for a significant new use, and an opportunity to protect against potentially adverse exposure before it occurs.

EFFECTIVE DATE: This rule becomes effective on November 20, 1996. Persons who begin commercial manufacture, importation, or processing of listed benzidine-based chemical substances for any significant new use listed in this rule between August 30, 1995, and November 20, 1996 must comply with the requirements of this final SNUR. See Unit VII of this preamble for more information. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on October 21, 1996.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxic Substances, Environmental Protection Agency, 401 M St., SW., Rm. E–545, Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This SNUR requires persons to notify EPA at