Regulatory Flexibility Act

This proposed amendment is certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) not to have a significant economic impact on a substantial number of small entities.

Drafting Information

The principal author of this document was Michael Smith, Regulations and Disclosure Law Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 141

Customs duties and inspection; Imports.

Proposed Amendment

It is proposed to amend part 141, Customs Regulations (19 CFR part 141), as set forth below:

PART 141—ENTRY OF MERCHANDISE

1. The authority citation for part 141 is revised in part to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

* * *

Section 141.1 also issued under 11 U.S.C. 507(a)(7)(F), 31 U.S.C. 191, 192;

* * * * *

2. In § 141.1 paragraph (c) is revised to read as follows:

§ 141.1 Liability of importer for duties.

* * * * *

(c) *Claim against estate of importer.* The claim of the Government for unpaid duties against the estate of a deceased or insolvent importer has priority over obligations to creditors other than the United States. To the extent that a broker or a surety pays duties on behalf of an importer which files for bankruptcy protection, the broker or surety shall be entitled to assume the priority status of Customs under section 507(a)(7)(F) of the Bankruptcy Code on a *pro rata* basis on the total amount due Customs.

Carol Hallett,

Commissioner of Customs.

Approved: February 28, 1991

John P. Simpson,

Acting Assistant Secretary of the Treasury.

[FR Doc. 91-5256 Filed 3-5-91; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N-0200]

RIN 0905-AA06

Warning Statements Required for Over-the-Counter Drugs Containing Water-Soluble Gums as Active Ingredients; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; clarification.

SUMMARY: The Food and Drug Administration (FDA) is issuing a clarification of its notice of proposed rulemaking requiring a warning in the labeling of all over-the-counter (OTC) drug products containing as active ingredients water-soluble gums, including guar gum, alerting users of these products to consume adequate fluid and to avoid using such products if the person has previously experienced any difficulty in swallowing. The intent of this document is to make it clear that the addition of this proposed warning statement in product labeling is not a sufficient basis to permit the continued marketing of OTC weight control drug products containing guar gum.

DATES: Written comments by April 5, 1991.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 30, 1990 (55 FR 45782), FDA proposed to require a warning for all OTC drug products containing water-soluble gums, e.g., guar gum, as active ingredients. The required warning would state the following:

Warning: (Select one of the following, as appropriate: Take or mix) this product with at least 8 ounces (a full glass) of water or other fluid. Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have ever had difficulty in swallowing or have any throat problems. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.

In the same issue of the **Federal Register**, the agency issued another notice of proposed rulemaking stating that certain ingredients in OTC weight control drug products are not generally recognized as safe and effective and are misbranded (55 FR 45788). In that proposal, the agency reclassified guar gum into Category II (not generally recognized as safe and effective) (55 FR 45788 at 45790 to 45791). FDA stated that data indicate a safety hazard of esophageal obstruction from the use of weight control drug products containing guar gum. The agency mentioned that it had issued a number of regulatory letters to manufacturers of weight control drug products containing guar gum and requested the manufacturers to cease distribution of such products.

In this notice the agency makes clear that the addition, in product labeling, of the proposed warning statement for water-soluble gums (55 FR 45782) does not permit marketing of OTC weight control drug products containing guar gum. FDA has taken, and will continue to take, regulatory action to remove these hazardous products from the marketplace.

Dated: February 26, 1991.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 91-5233 Filed 3-5-91; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

Ohio Regulatory Program; Revision of Administrative Rules

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening of public comment period; withdrawal of previously proposed amendment.

SUMMARY: OSM is reopening the public comment period on Revised Program Amendment Number 43 to the Ohio permanent regulatory program (hereinafter referred to as the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Ohio has proposed further revisions to four rules which are intended to make those rules as effective as the corresponding Federal