Proposed Rules

Federal Register
Vol. 73, No. 240
Friday, December 12, 2008

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 360

[Docket Number 0809261282–81283–01]

RIN 0625–AA82

Steel Import Monitoring and Analysis System

AGENCY: Import Administration, International Trade Administration, Commerce.

ACTION: Proposed rule.

SUMMARY: The Department of Commerce publishes this proposed rule to request public comment on modifications to the Steel Import Monitoring and Analysis (SIMA) System. These modifications are proposed to extend the current SIMA system until March 21, 2013. This extension would continue the Department's ability to track steel imports and make them publicly available in advance of the full trade data release.

DATES: Comments must be submitted on or before 5 p.m. EST, January 12, 2009.

ADDRESSES: Comments on the SIMA system may be submitted through any of the following:

- *Mail:* Kelly Parkhill, Director for Industry Support and Analysis, Import Administration, Room 3713, Department of Commerce, 14th and Constitution Ave., NW., Washington, DC 20230.
- *E-mail: steel_license@ita.doc.gov*. Please state ''Comments on the 2008 Proposed Rule'' in the subject line.
- *Federal e-Rulemaking portal: http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: For information on the SIMA system, please contact Kelly Parkhill (202) 482–3791; Julie Al-Saadawi (202) 482–1930.

SUPPLEMENTARY INFORMATION: An interim final rule revising part 360 was published in the **Federal Register** March 11, 2005, 70 FR 12136. On December 5, 2005, the Department of Commerce published its final rule on the current SIMA system (70 FR 72373). Under the final rule, the system expires on March 21, 2009, unless extended upon review and notification in the **Federal Register**.

The purpose of the SIMA system is to provide steel producers, steel consumers, importers, and the general public with accurate and timely information on anticipated imports of certain steel products. Import licenses, obtained through the Internet-based SIMA licensing system, are required on U.S. imports of basic steel mill products. Aggregate import data obtained from the licenses is updated weekly and posted on the SIMA Web site monitor. Details of the current system can be found at *http://ia.ita.doc.gov/steel/license/*.

Proposal: The Department proposes to extend the SIMA system beyond its current expiration date for an additional period of four years (see 19 CFR part 360).

All comments responding to this notice will be a matter of public record and available for public inspection and copying at Import Administration's Central Records Unit, Room 1117, between the hours of 8:30 a.m. and 5 p.m. on business days.

Classification

Regulatory Flexibility Act. The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities as that term is defined in the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* A summary of the factual basis for this certification is below.

This proposed rule will not have a significant economic impact on a substantial number of companies. Companies are already familiar with the licensing of certain steel products under the current system. In most cases, brokerage companies will apply for the license for the steel importers. Most brokerage companies that are currently involved in filing documentation for importing goods into the U.S., are accustomed to Customs and Border Protection's automated systems. Today, more than 99% of the Customs filings are handled electronically. Therefore, the Web-based nature of this simple license application should not be a significant obstacle to any firm in completing this requirement. However, should a company need to apply for an ID or license non-electronically, a fax/phone option will be available at Commerce during regular business hours. There is no cost to register for a company-specific ID user code and no cost to file for the license. Each license form is expected to take less than 10 minutes to complete using much of the same information used to complete the Customs Entry Summary documentation. This is the one additional requirement of the importers or their representative to fulfill U.S. entry requirements to import each covered steel product shipment. Commerce estimates that fewer than five percent of the licenses would be filed by brokerage companies or other businesses that would be considered small entities. Therefore, Commerce estimates that the likely aggregate license costs attributable to small entities would be one percent of the estimated total $2,000,000 cost to all steel importers, or $20,000 would represent the cost that small entities will incur as a result of this proposed rule.

Paperwork Reduction Act. This proposed rule contains collection-of-information requirements subject to review and approval by OMB under the Paperwork Reduction Act (PRA). These requirements have been approved by OMB (OMB No.: 0625–0245; Expiration Date: 09/30/2011). Public reporting for this collection of information is estimated to be less than 10 minutes per response, including the time for reviewing instructions, and completing and reviewing the collection of information.

Paperwork Reduction Act Data:
OMB Number: 0625–0245.
ITA Number: ITA–4141P.
Type of Review: Regular Submission.
Affected Public: Business or other for-profit.
Estimated Number of Registered Users: 3,500.
Estimated Time per Response: Less than 10 minutes.
Estimated Total Annual Burden Hours: 100,000 hours.
Estimated Total Annual Costs: $2,000,000.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a

penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number.

Executive Order 12866

This rule has been determined to be significant for purposes of Executive Order 12866.

Executive Order 13132

This rule does not contain policies with federalism implications as that term is defined in EO 13132.

List of Subjects in 19 CFR Part 360

Administrative practice and procedure, Business and industry, Imports, Reporting and recordkeeping requirements, Steel.

For reasons discussed in the preamble, we propose amending 19 CFR 360 as follows:

PART 360—STEEL IMPORT MONITORING AND ANALYSIS SYSTEM

1. The authority citation for part 360 continues to read as follows:

Authority: 13 U.S.C. 301(a) and 302.

2. Section 360.105 is revised to read as follows.

§ 360.105 Duration of the steel import licensing requirement.

The licensing program will be in effect through March 21, 2013, but may be extended upon review and notification in the **Federal Register** prior to this expiration date. Licenses will be required on all subject imports entered during this period, even if the entry summary documents are not filed until after the expiration of this program. The licenses will be valid for 10 business days after the expiration of this program to allow for the final filing of required Customs documentation.

Dated: November 26, 2008.

Christopher A. Padilla,

Under Secretary for International Trade.

[FR Doc. E8–28683 Filed 12–11–08; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2008–N–0622]

Withdrawal of Certain Proposed Rules and Other Proposed Actions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a certain advance notice of proposed rulemaking (ANPRM) and proposed rules (NPRMs) that published in the **Federal Register** more than 5 years ago. These proposals are no longer considered viable candidates for final action at this time.

DATES: The proposals identified in this document are withdrawn as of December 12, 2008.

FOR FURTHER INFORMATION CONTACT:

For Center for Drug Evaluation and Research actions: Michael D. Bernstein, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6240, Silver Spring, MD 20993–0002, 301–796–3478.

For Center for Food Safety and Nutrition actions: Felicia Ellison, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1264.

For all other actions: Erik Mettler, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., WO1, Rm. 4324, Silver Spring, MD 20993, 301–796–4830.

SUPPLEMENTARY INFORMATION:

I. Background

In 1990, the Food and Drug Administration (FDA) began the process of conducting periodic, comprehensive reviews of its regulations process that included reviewing the backlog of ANPRMs, notices of proposed rulemaking, and other notices for which no final action or withdrawal notice had been issued. In the **Federal Register** of December 30, 1991 (56 FR 67440), FDA issued its first notice withdrawing 89 proposed rules that had published before December 31, 1985, but had never been finalized. Then again, in the **Federal Register** of January 20, 1994 (59 FR 3042), the agency withdrew an additional nine outstanding proposed rules.

FDA published a notice in the **Federal Register** of April 22, 2003 (68 FR 19766), announcing its intent to withdraw 84 proposed rules and other proposed actions that had published in the **Federal Register** more than 5 years ago, but that had never been finalized. Included in this list were 19 proposed rules that were originally proposed for withdrawal in 1991, but at that time the agency decided to defer its decision to withdraw or finalize them until a later date. In the **Federal Register** of November 26, 2004 (69 FR 68831), the agency withdrew 81 proposed rules and other proposed actions.

The agency has conducted another review of its regulations process and found withdrawal is justified for four proposals.

II. NPRMs and ANPRMs To Be Withdrawn

Title: Labeling Declaration for FD&C Yellow No. 6 and FD&C Yellow No. 5; Amendment of Standard of Identity for Cheese Product (Proposed Rule, 92N–0334 (60 FR 37611, July 21, 1995))

Reason: Since the publication of this proposal, the underlying science and economic analyses have become outdated.

Title: Over-the-Counter Drug Products Containing Phenylpropanolamine; Required Labeling (Proposed Rule, 95N–0060 (61 FR 5912, February 14, 1996))

Reason: The agency's ''Over-the-Counter Drug Products Containing Phenylpropanolamine; Required Labeling'' (Proposed Rule, 95N–0060 (61 FR 5912, February 14, 1996)) has been superseded by the issuance of a new proposed rule entitled ''Phenylpropanolamine-Containing Drug Products for Over-the-Counter Human Use; Tentative Final Monographs'' (1976N–0052N and 1981N–0022 (70 FR 75988, December 22, 2005)).

Title: Reinvention of Administrative Procedures Regulations (ANPRM, 96N–0163 (61 FR 28116, June 4, 1996))

Reason: The ANPRM requested comments on whether there should be possible changes to various existing administrative regulations under the ''Reinventing Government'' initiative. Since publication, some of the regulations have been addressed in separate rulemakings. The remaining regulations are not under current consideration for rulemaking.

Title: Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs (Proposed Rule, 99N–3088 (65 FR 3623, January 24, 2000))