DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 7, and 16

[Docket No. FDA–2011–N–0121]

RIN 0910–AG60

Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). With these amendments, tobacco products will be subject to the same general requirements that apply to other FDA-regulated products.

DATES: Submit either electronic or written comments on the proposed rule by June 13, 2011. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by May 16, 2011, (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0121 and/or Regulatory Information Number (RIN) number 0910–AG60, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0121 and RIN 0910–AG60 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–CTP–1373, *gerie.voss@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and providing FDA with the authority to regulate tobacco products (Pub. L. 11–31; 123 Stat. 1776). In enacting the Tobacco Control Act, Congress sought to ensure that FDA had authority to provide effective oversight and to impose appropriate regulatory controls on the tobacco industry. In order to effectuate these purposes, FDA is seeking to amend several provisions of its general regulations to reflect the Agency's new authority and mandate regarding tobacco products.

II. Legal Authority

FDA is issuing this proposed rule under provisions of the FD&C Act, as amended by the Tobacco Control Act (21 U.S.C. 321, 331, 333, 371, 381, 387, 387a, 387c, 387f, 387j and 387k); FDA is also issuing this proposed rule under section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) as amended by the Tobacco Control Act and under section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) as amended by the Tobacco Control Act.

II. Description of Proposed Regulations

FDA proposes to make the following amendments to title 21 of the Code of Federal Regulations (CFR), reflecting the Agency's authority over tobacco products under the Tobacco Control Act:

1. Add "tobacco products" to the list of products covered by § 1.21(a) and (c)(1) (21 CFR 1.21(a) and (c)(1)) and § 1.101(a) and (b) (21 CFR 1.101(a) and (b));
2. Revise the definition of "product" in § 7.3(f) (21 CFR 7.3(f)) to include tobacco products; and
3. Revise § 16.1(b) (21 CFR 16.1(b)) to add provisions from the Tobacco Control Act that allow for hearings.

A. Section 1.21—Failure To Reveal Material Facts

Section 1.21(a) states that the labeling of FDA-regulated products shall be deemed misleading if it fails to reveal facts that are: "* * * Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or [m]aterial with respect to consequences which may result from use of the article under: The conditions prescribed in such labeling or such conditions of use as are customary or usual." FDA is proposing to amend § 1.21(a) to provide that tobacco product labeling also would be deemed misleading for similar failures to reveal material facts. See section 903(a) of the Tobacco Control Act (21 U.S.C. 387c(a)) (stating that a tobacco product shall be deemed to be misbranded if its labeling is false or misleading). See also section 201(n) of the FD&C Act (21 U.S.C. 321(n)).

Section 1.21(c) describes statements that are not permissible on labeling for FDA-regulated products. For example, paragraph (c)(1) explains that this regulation does not "[p]ermit a statement of differences of opinion with respect to warnings * * *" on FDA-regulated products. The proposed rule would amend this paragraph to state that tobacco product labeling, like the labeling of other FDA-regulated products, also may not have a statement of differences of opinion regarding the warnings on tobacco packages or advertisements. This change is in accordance with sections 201 and 204 of the Tobacco Control Act, amending the FCLAA, and the CSTHEA, respectively, as well as section 903(a) generally. FDA already has initiated a rulemaking proceeding to implement section 201 of the Tobacco Control Act, amending 15 U.S.C. 1333). See the **Federal Register** of November 12, 2010 (75 FR 69524).

B. Section 1.101—Notification and Recordkeeping

Section 1.101 outlines the notification and recordkeeping requirements for exports of FDA-regulated products.

Section 1.101(a) pertains to all notifications and records required for FDA-regulated products that may be exported under section 801 or 802 of the FD&C Act (21 U.S.C. 381 and 382) and section 351 of the Public Health Service Act (42 U.S.C. 262). Because section 103(l) of the Tobacco Control Act specifically amends section 801 of the FD&C Act to include "tobacco products" on the list of FDA-regulated products that may be exported under this section, the proposed rule would amend § 1.101(a) and (b) to indicate that tobacco products exported under section 801(e)(1) of the FD&C Act also would be subject to the recordkeeping requirements of this regulation. Please note that this revision to § 1.101(b) does not alter the exercise of enforcement discretion described in the advance notice of proposed rulemaking that published in the **Federal Register** of June 1, 2004 (69 FR 30842).

C. Section 7.3—Definitions

Section 7.3 defines the term "product" to include all the specific items that are subject to FDA's jurisdiction. The proposed change to § 7.3 of the regulations would define "product" to also include tobacco products.

D. Section 16.1—Scope

Section 16.1(b) lists the statutory and regulatory provisions that provide for the opportunity for a regulatory hearing. Sections 903(a)(8)(B)(ii), 906(e)(1)(B), 910(d)(1), and 911(j) of the Tobacco Control Act all provide for the opportunity for a hearing. The proposed rule would amend § 16.1 to include certain instances in the Tobacco Control Act where an opportunity for a hearing is provided.

IV. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). 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 proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed requirements are likely to impose a burden on a substantial number of affected small entities, the Agency proposes to certify that the final rule will have a significant economic impact on a substantial number of small entities and has conducted an Initial Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

FDA has not quantified the benefits of this proposed rule. This proposed rule would impose compliance costs on producers of tobacco products as they would have to comply with recordkeeping requirements according to general regulations that apply to other products that FDA regulates. The estimated annual costs of complying with these requirements range from $71,438 to $376,242.

B. Need for the Proposed Rule

The Tobacco Control Act grants FDA authority to regulate tobacco products, thereby enabling FDA to assess the effects of tobacco products on the public health.

The proposed amendments would ensure tobacco manufacturers adhere to the regulations that apply to other FDA-regulated products sold in the United States, and exports of products that are not allowed for sale in the United States. The proposed rule clarifies FDA's practices and procedures with respect to voluntary recalls of tobacco products. It also guarantees that tobacco product manufacturers have the same rights as other FDA-regulated entities, where appropriate, such as the right to regulatory hearings.

C. Benefits

FDA is unable to quantify the benefits of the proposed amendments. Benefits would derive from FDA's enhanced ability to carry out its obligations, and from clarifying certain FDA practices and procedures for tobacco product manufacturers.

D. Costs

Section 7.3(f) clarifies and explains FDA's practices and procedures with respect to recalls of tobacco products. FDA tentatively concludes that tobacco product manufacturers follow recall procedures consistent with current regulations and that the proposed amendment to § 7.3(f) would not impose additional burdens on tobacco product manufacturers.[1] The proposed revision to § 16.1(b) allows for an informal hearing when FDA is considering regulatory actions or decisions related to misbranding, good manufacturing practice requirements or withdrawal of a tobacco product. No additional costs are expected to accrue from amendments to §§ 1.21(c), 7.3(f), and 16.1(b).

Additional costs would derive from recordkeeping requirements as they relate to some tobacco product exports (§§ 1.101(a) and (b)). The estimated annual costs range is between $0.07 million and $0.37 million, as further explained in table 1 of this document.

TABLE 1—TOTAL ESTIMATED COSTS OF RULE

Cost factor	Annual cost	
	Low	High
Exports of Tobacco Products	$71,438	$376,242

Sections 1.101(a) and (b) pertain to recordkeeping of documentation that demonstrates that tobacco products not allowed for sale in the United States are exported in accordance with appropriate regulations. In addition, recordkeeping documents must demonstrate that: (1) The product meets the foreign purchaser's specifications; (2) the product does not conflict with the laws of the foreign country; (3) correct labeling is placed outside of the shipping package; and (4) the product is not sold or offered in the United States. These documents are required to be retained (§ 1.101(b)).

1. Number of Affected Entities

The U.S. Department of Commerce International Trade Administration (ITA) reports that the total number of

[1] In 1995, a major tobacco product manufacturer voluntarily recalled a few tobacco product lines when it was found that the products might be contaminated. After several investigations a Centers for Disease Control and Prevention (CDC) report concluded that it was the use of the tobacco product and not the contaminated product that caused the health complaints (Ref. 1).

(manufacturing and nonmanufacturing) U.S. companies exporting tobacco products (North American Industry Classification System or NAICS code 3122) to the world in 2007 was 158, which includes 30 manufacturers and 125 nonmanufacturers of tobacco products.[2] Exporting manufacturers represent approximately 38 percent of all manufacturing companies reported by the 2007 Economic Census in this NAICS category (Ref. 3). FDA takes the total number of exporting manufacturing companies as a lower bound and the total number of exporting (manufacturing and nonmanufacturing) companies as an upper bound for the total number of respondents that would be affected by the proposed rule.

2. Estimated Economic Costs on Affected Entities

In estimating the burden, FDA uses the number of responses per respondent (3), and time per response (2 hours for recordkeeping) from previously reported estimates relating to drugs and medical devices (73 FR 46007, August 7, 2008). In valuing the time cost, FDA uses the 2009 median hourly wage of $18.04 for Office and Administrative Support Occupations (Standard Occupational Classification code 430000) in the tobacco manufacturing industry (NAICS code 312200) as reported by the Bureau of Labor Statistics (Ref. 4), plus benefits and overhead. Table 2 of this document shows that annual recordkeeping costs for all respondents are estimated to be between $0.07 million and $0.37 million.

TABLE 2—ESTIMATED INCREMENTAL BURDEN FOR EXPORTERS

Cost factor	Number of recordkeepers	Responses per recordkeeper	Total annual records	Hours per recordkeeper	Annual cost low—high
Recordkeeping	30 to 158	3	90 to 474	2	$71,438 to $376,242.

E. Analysis of Alternatives

The simplest alternative would be to exempt exporters of tobacco products from the proposed recordkeeping requirements according to general regulations that apply to other exports that FDA regulates. Under this option, there would be no immediate compliance costs or benefits. Compliance costs for exporters of tobacco products are estimated to be between $0.07 million and $0.37 million. The proposed recordkeeping requirements for exporters of tobacco products would have the benefit of allowing FDA to carry out its obligations and to clarify practices and procedures for tobacco product manufacturers.

F. Initial Regulatory Flexibility Act Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. This analysis serves as the Initial Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act.

1. Description and Number of Affected Small Entities

The U.S. Small Business Administration (SBA) uses different definitions of what a small entity is for different industries. Using 2009 SBA size standard definitions, a firm categorized in NAICS code 312229 (Other Tobacco Product Manufacturing) is considered small if it hires fewer than 500 employees. On the other hand, firms classified in NAICS code 312221 (Cigarette Manufacturing) are considered small if they hire fewer than 1,000 employees (Ref. 5).

The most current available data on the number of establishments by employee size have not been released for the categories listed previously; thus, FDA uses data from the 2002 Economic Census (Ref. 6) to determine the number of small entities. FDA notes that the data are available at the establishment level rather than at the firm level, and assumes that the typical manufacturing establishment is roughly equivalent to the typical small manufacturing firm. Statistics on the classification of establishments by employment size show that in the year 2002, 67 to 99 percent of tobacco manufacturing entities had fewer than 1,000 employees and would be considered small by SBA. (See table 3 of this document.)

TABLE 3—ESTIMATED NUMBER OF SMALL ENTITIES AFFECTED

	Cigarette manufacturing (NAICS 312221)	Other tobacco product manufacturing (NAICS 312229)
Size Standards in Number of Employees	< 1,000	< 500
Total Number of Establishments	15	83
Percent Considered Small	67%	99%
Estimated Number of Affected Entities	2	12

FDA also estimates the percent of small to medium-sized [3] exporting companies to be 15 percent, using industry trade data for NAICS code 3122 (Tobacco Products) made available by ITA. The estimated number of affected exporting entities is determined by multiplying 0.15 by the total number of establishments. The estimates indicate that the estimated number of affected entities would range between 2 and 12 exporters. (See table 3 of this document.)

[2] As firms sometimes export multiple products, a single firm can be represented in multiple products; thus, exporter counts may not add up to the total (Ref. 2).

[3] ITA defines small firms as those with fewer than 100 employees and medium-sized firms as those that employ from 100 to 499 workers (Ref. 7).

2. Economic Effect on Small Entities

FDA uses the total value of shipments data by employment size from the 2002 Economic Census published by the U.S. Bureau of the Census to determine the unit cost as a percent of the total value of shipment for a typical manufacturer. The analysis of the effect on small versus large entities is limited by the U.S. Bureau of the Census data restrictions imposed to safeguard the confidentially of some establishments in NAICS code 312221. Consequently, the average value of shipments is presented for all establishments in NAICS code 312221 and for establishments employing 1 to 19 and 20 to 99 employees, separately. The average cost per entity is $2,814. It is estimated that this average cost as a percent of average value of shipments for small entities may be between 0.00 and 0.31 percent (see table 4). The Agency tentatively concludes that this proposed rule would have a significant economic impact on a substantial number of small entities, but the impact is uncertain.

TABLE 4—ESTIMATED AVERAGE VALUE OF SHIPMENTS FOR A TYPICAL MANUFACTURER

Description	NAICS		
	31221	31229	
Establishment Employee Size	All	1 to 19	20 to 99.
Value of Shipments ($1,000)	$34,562,900	$35,979	$270,348.
Number of Establishments	15	47	20.
Average Value of Shipments ($1,000)	$2,304,193	$766	$13,517.
Unit Cost as Percent of Average Value of Shipments	0.00%	0.31%	0.02%.

3. Additional Flexibility Considered

In this section, we discuss an alternative that would present possible reductions in costs which would be channeled through small entities. Exempting exporters of tobacco products from recordkeeping requirements would result in an estimated annual savings of 0.02 to 0.31 percent of the cost of the value of shipments for small-sized firms. However, these recordkeeping requirements would provide evidence that tobacco product manufacturers export according to regulations that apply to other FDA-regulated products.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Product Issues—21 CFR 1.101.

Description: On June 22, 2009, the President signed the Tobacco Control Act into law. In this proposed rule, FDA is amending certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Tobacco Control Act. The amendments in this proposed rulemaking will subject tobacco products to the same general requirements that apply to other FDA-regulated products, where appropriate.

This proposed rule would amend § 1.101(b), among other sections, to require persons who export human drugs, biologics, devices, animal drugs, cosmetics, and tobacco products that may not be sold in the United States to maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act. Section 801(e)(1) requires exporters to keep records demonstrating that the exported product: (1) Meets with the foreign purchaser's specifications; (2) does not conflict with the laws of the foreign country; (3) is labeled on the outside of the shipping package that is intended for export; and (4) is not sold or offered for sale in the United States. These criteria also could be met by maintaining other documentation, such as letters from a foreign government Agency or notarized certifications from a responsible company official in the United States stating that the exported product does not conflict with the laws of the foreign country.

Description of Respondents: Manufacturers, distributors, and other persons who export tobacco products not intended for sale in the United States.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN EXPORTERS OF TOBACCO PRODUCTS

21 CFR section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
1.101(b)	158	3	474	22	10,428

The Agency estimated the number of respondents and burden hours associated with the recordkeeping requirements by reviewing Agency records and using Agency expert resources, and conferring with another Federal Agency with experience and information regarding tobacco product exporters. FDA estimates that between

30 and 158 establishments could be involved in the exporting of tobacco products and, based on previous recordkeeping estimates in OMB control number 0910–0482, "Export Notification and Recordkeeping Requirements," each establishment may have to maintain records up to 3 times per year, at a total of 22 hours per recordkeeper. Therefore, the Agency estimates between 1,980 and 10,428 burden hours will be needed for tobacco product exporters to create and maintain records demonstrating compliance with section 801(e)(1) of the FD&C Act. Therefore, FDA estimates that 158 respondents will require approximately 10,428 hours to comply with the requirements of section 801(e)(1) of the FD&C Act.

VI. Executive Order 13132: Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Environmental Impact

The Agency has determined under 21 CFR 25.30(h), (i), and (k) 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.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on public display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested parties between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register.**

1. CDC, 1996, "Recall of Philip Morris Cigarettes, May 1995–March 1996," *Morbidity and Mortality Weekly Report,* 45(12): pp. 251–254, *http://www.cdc.gov/mmwr/preview/mmwrhtml/00041035.htm,* accessed November 2010.
2. ITA, 2010, "Industry Trade Data and Analysis," *http://www.trade.gov/mas/ian/EDB/Reports/2007/table14_allmarkets_allcategories.html,* last accessed November 2010.
3. U.S. Census Bureau American FactFinder, 2007, "Sector 31: EC0731I1: Manufacturing: Industry Series: Detailed Statistics by Industry for the United States: 2007," *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC0231I4&-_lang=en,* accessed October 2010.
4. U.S. Bureau of Labor Statistics, 2009, "Occupational Employment Statistics," *http://data.bls.gov/oes,* accessed October 15, 2010.
5. SBA, 2010, "Table of Small Business Size Standards Matched to North American Industry Classification System Code," *http://www.sba.gov/content/table-small-business-size-standards,* accessed March 2, 2011.
6. U.S. Census Bureau American FactFinder, 2002, "2002 Economic Census: Sector 31: Manufacturing: Industry Series: Industry Statistics by Employment Size: 2002," *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC0231I4&-_lang=en,* accessed October 2010.
7. ITA, *http://www.trade.gov/mas/ian/smeoutlook/edbtechnicalnotes/tg_ian_001929.asp,* last accessed November 2010.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 7

Administrative practice and procedure, Consumer protection, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1, 7, and 16 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Amend § 1.21 by revising paragraph (a) introductory text and paragraph (c)(1) to read as follows:

§ 1.21 Failure to reveal material facts.

(a) Labeling of a food, drug, device, cosmetic, or tobacco product shall be deemed to be misleading if it fails to reveal facts that are:

* * * * *

(c) * * *

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, cosmetics, or tobacco products under the Federal Food, Drug, and Cosmetic Act.

* * * * *

3. Amend § 1.101 by revising paragraph (a) and the heading of paragraph (b) to read as follows:

§ 1.101 Notification and recordkeeping.

(a) *Scope.* This section pertains to notifications and records required for human drug, biological product, device, animal drug, food, cosmetic, and tobacco product exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act or (21 U.S.C. 381 and 382) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) *Recordkeeping requirements for human drugs, biological products, devices, animal drugs, foods, cosmetics, and tobacco products exported under or subject to section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act.* * * *

* * * * *

PART 7—ENFORCEMENT POLICY

4. The authority citation for part 7 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

5. Amend § 7.3(f) by revising the first sentence to read as follows:

§ 7.3 Definitions.

* * * * *

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food,

drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, any tobacco product intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. * * *

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

6. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

7. Amend § 16.1 by adding new statutory provisions to the end of paragraph (b)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 903(a)(8)(B)(ii) of the Federal Food, Drug, and Cosmetic Act relating to the misbranding of tobacco products.

Section 906(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act relating to the establishment of good manufacturing practice requirements for tobacco products.

Section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a new tobacco product to be introduced or delivered for introduction into interstate commerce.

Section 911(j) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a modified risk tobacco product to be introduced or delivered for introduction into interstate commerce.

* * * * *

Dated: April 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9044 Filed 4–13–11; 8:45 am]

BILLING CODE 4160–01–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2011–9; Order No. 713]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking; availability of rulemaking petition.

SUMMARY: The Commission is establishing a docket to consider a proposed change in certain analytical methods used in periodic reporting. This action responds to a Postal Service rulemaking petition. Establishing this docket will allow the Commission to consider the Postal Service's proposal and comments from the public.

DATES: *Comments are due:* May 9, 2011.

ADDRESSES: Submit comments electronically by accessing the "Filing Online" link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: On April 6, 2011, the Postal Service filed a petition pursuant to 39 CFR 3050.11 asking the Commission to initiate an informal rulemaking proceeding to consider changes in the analytical methods approved for use in periodic reporting.[1]

Proposal One[2] would propose to modify the attribution of costs for Fee Group E Post Office Boxes so that the costs are considered institutional rather than as part of the attributable costs of Post Office Box Service. The Postal Service asserts that its aim is to achieve more equitable financing of Fee Group E Post Office Boxes. It notes that the proposal has no impact on the methodology for the calculation of costs for Fee Group E Post Office Boxes. *Id.* at 1.

The Postal Service states that under this proposal, Group E costs would be paid for by all mailers, not just post office box holders. It maintains that the Group E costs methodology remains consistent with Docket No. ACR2010 and Docket No. MC2010–20. *Id.* Attachment at 1.

The Attachment to the Postal Service's Petition explains its proposal in more detail, including its background, objective, rationale, and estimated impact. The Petition, including the attachments, is available for review on the Commission's Web site, *http://www.prc.gov.*

Pursuant to 39 U.S.C. 505, James F. Callow is designated as Public Representative to represent the interests of the general public in this proceeding. Comments are due no later than May 9, 2011.

It is ordered:

1. The Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider Proposed Changes in Analytic Principles (Proposal One), filed April 6, 2011, is granted.

2. The Commission establishes Docket No. RM2011–9 to consider the matters raised by the Postal Service's Petition.

3. Interested persons may submit comments on Proposal One no later than May 9, 2011.

4. The Commission will determine the need for reply comments after review of the initial comments.

5. James F. Callow is appointed to serve as the Public Representative to represent the interests of the general public in this proceeding.

6. The Secretary shall arrange for publication of this Notice in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2011–9058 Filed 4–13–11; 8:45 am]

BILLING CODE 7710–FW–P

[1] Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider Proposed Changes in Analytic Principles (Proposal One), April 6, 2011 (Petition).

[2] This is the first proposal filed after the FY 2010 Annual Compliance Report. It is the Postal Service's current practice to restart its proposal numbering sequence.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–0998; FRL–9295–4]

Approval and Promulgation of Air Quality Implementation Plans; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a request submitted by the Indiana Department of Environmental Management on November 24, 2010, to revise the Indiana State Implementation Plan (SIP) under the Clean Air Act. Indiana submitted revisions to the particulate matter (PM) and sulfur dioxide (SO_2) limits for Cargill, Incorporated (Cargill) at its facility in Hammond (Lake County), Indiana. Indiana's SO_2 revisions tighten emission limits for some existing units at Cargill's Hammond facility and remove the references to other emission units that are no longer in operation, in