



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: Final rule.

SUMMARY: The Food and Drug Administration (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 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). With these amendments, tobacco products are subject to the same general requirements that apply to other FDA-regulated products.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of April 14, 2011 (76 FR 20901), FDA issued a proposed rule seeking to amend several provisions of its general regulations to reflect the Agency's new authority and mandate regarding tobacco products under the Tobacco Control Act (Public Law 11-31; 123 Stat. 1776). FDA received substantive comments to its proposal from only one commenter. However, FDA does not believe that these comments warrant making any changes to the regulatory language included in the proposed rule.

Relevant portions of these comments are summarized and responded to in the relevant section(s) of this document. To make it easier to identify comments and FDA's responses, the word "Comment," in brackets, appears before the comment's description, and the word "Response," in brackets, appears before FDA's response. Each comment is numbered to help distinguish among different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance.

II. Legal Authority

FDA is issuing this final rule under provisions of the Federal Food, Drug, and Cosmetic Act (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 final 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 (CSTHEA) (15 U.S.C. 4402) as amended by the Tobacco Control Act.

III. Description of Final Regulations

With this rule, FDA is finalizing several amendments to title 21 of the Code of Federal Regulations (CFR), reflecting the Agency's authority over tobacco products under the Tobacco Control Act. The amendments are described in sections III.A, III.B, and III.C of this document.

A. Section 1.21--Failure to Reveal Material Facts

Section 1.21(a) (21 CFR 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." With this final rule, FDA is amending § 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. This final rule amends this section 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 issued a final

rule to implement section 201 of the Tobacco Control Act, amending 15 U.S.C. 1333. See the Federal Register of June 22, 2011 (76 FR 36628).

B. Section 1.101--Notification and Recordkeeping

Section 1.101 (21 CFR 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 sections 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, this final rule amends § 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 enforcement policy described in the advance notice of proposed rulemaking that published in the Federal Register of June 1, 2004 (69 FR 30842). Thus, with regard to tobacco products, FDA intends to exercise enforcement discretion, as it does with exports generally, regarding the requirement for specific types of records under § 1.101(b)(2) demonstrating that the exported product is not in conflict with the foreign country's laws.

(Comment 1)--One comment requested that FDA provide notice and an opportunity to comment should it propose to end this period of enforcement discretion as it applies to tobacco products.

(Response 1)--We note, previously, that this revision does not alter our exercise of enforcement discretion, including with respect to tobacco products and additional notice and comment with respect to this issue is not necessary.

C. Section 7.3--Definitions

Section 7.3 (21 CFR 7.3) defines the term "product" to include all the specific items that are subject to FDA's jurisdiction. This final rule amends § 7.3 of the regulations to define "product" to also include tobacco products.

(Comment 2)--One comment stated that FDA's proposed change to § 7.3 did not take into account the fundamental differences between tobacco products and other regulated product categories and, therefore, it should be amended accordingly. This comment also requested that FDA make additional changes to part 7.

(Response 2)--FDA believes that its change to § 7.3 is necessary to ensure that tobacco products are subject to the same general requirements that apply to other FDA-regulated products. The differences between tobacco products and other regulated products do not warrant any additional changes to § 7.3. In circumstances where FDA's requirements apply solely to tobacco products, that is noted in the appropriate sections of the Agency's regulations. Further, FDA believes that the other suggested revisions to part 7 included in this comment are beyond the scope of this rulemaking.

D. Section 16.1--Scope

Section 16.1(b) (21 CFR 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 final rule amends § 16.1 to include certain instances in the Tobacco Control Act where an opportunity for a hearing is provided.

(Comment 3)--One comment requested that FDA also amend part 16 (21 CFR part 16) to provide an opportunity for a regulatory hearing if FDA were to issue a Not Substantially

Equivalent (NSE) determination for a tobacco product introduced between February 15, 2007, and March 22, 2011.

(Response 3)--FDA declines to adopt this change. FDA is amending part 16 to incorporate those specific circumstances in which the Tobacco Control Act expressly provides for notice and an opportunity for hearing. Section 910 of the Tobacco Control Act does not specifically provide for notice and an opportunity for hearing with respect to NSE orders; therefore, FDA declines to add section 910(a)(2)(B) to the list of circumstances that provide for a part 16 hearing.

IV. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct 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 will not be a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the requirements are likely to impose a burden on a substantial number of affected small entities, the Agency anticipates that the final rule will have a significant economic impact on a substantial number of

small entities and has conducted a Final 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 \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

FDA has not quantified the benefits of this final rule. This rule will impose compliance costs on producers of tobacco products as they will be required to comply with recordkeeping requirements according to general regulations that apply to other products that FDA regulates. FDA updates the estimated costs presented in the proposed rule published in the Federal Register of April 14, 2011, to incorporate the most recent and publicly available wage rate data. The estimated annual costs of complying with these requirements range from \$71,201 to \$374,991.

B. Need for the Regulation

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 final rule ensures 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 final 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 amendments. Benefits will 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 concludes that tobacco product manufacturers follow recall procedures consistent with current regulations and that the amendment to § 7.3(f) will not impose additional burdens on tobacco product manufacturers.¹ The 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 will derive from recordkeeping requirements as they relate to some tobacco product exports (§ 1.101(a) (b)). The estimated annual costs range is between \$0.07 million and \$0.37 million, as further explained in table 1 of this document.

Cost factor	Annual cost	
	Low	High
Exports of Tobacco Products	\$71,201	\$374,991

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).

Section 1.101(a) (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 (manufacturing and non-manufacturing) 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 non-manufacturers 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 non-manufacturing) companies as an upper bound for the total number of respondents that will be affected by the final 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 (22 hours for recordkeeping)³ from previously reported estimates relating to drugs and medical devices (August 7, 2008, 73 FR 46007). In valuing the time cost, FDA uses the

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 The proposed rule inadvertently listed 2 hours for recordkeeping in this section. The total economic effect, however, was accurate and the proper number of 22 hours was listed in the Paperwork Reduction Act (PRA) section.

2010 median hourly wage of \$17.98 for Office and Administrative Support Occupations (NAICS 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	22	\$71,201 to \$374,991

E. Analysis of Alternatives

The simplest alternative is to exempt exporters of tobacco products from the 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 recordkeeping requirements for exporters of tobacco products will have the benefit of allowing FDA to carry out its obligations and to clarify practices and procedures for tobacco product manufacturers.

F. Final Regulatory Flexibility Act Analysis

FDA has examined the economic implications of this final 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 Final Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act.

1. Description and Number of Affected Small Entities

The 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 in this document; 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 will 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-sized⁴ 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

⁴ 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).

the total number of establishments. The estimates indicate that the estimated number of affected entities ranges between 2 and 14 exporters. (See table 3 of this document.)

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 confidentiality 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 of this document). The Agency concludes that this final rule will have a significant 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 to reduce costs for small entities. Exempting exporters of tobacco products from recordkeeping requirements can 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 will provide evidence that tobacco product manufacturers export according to regulations that apply to other FDA-regulated products.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are 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.

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 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 rulemaking will subject tobacco products to the same general requirements that apply to other FDA-regulated products, where appropriate.

This rule amends § 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.

Comments: A few comments were received which were beyond the scope of this collection of information, did not address PRA issues, and were not addressed in this rule.

Table 5.--Estimated Annual Recordkeeping Burden
Exporters of Tobacco Products

21 CFR Section	No. 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 estimates 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. 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.

The information collection provisions of this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA.

Before the effective date of this final rule, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Executive Order 13132: Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that this final rule does not contain policies that 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 concludes that this final 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. 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): 251-254,

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00041035.htm>, last 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: EC073111:

Manufacturing: Industry Series: Detailed Statistics by Industry for the United States: 2007,”

http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC073111&-lang=en, last accessed October 2010.

4. U.S. Bureau of Labor Statistics, 2010, “Occupational Employment Statistics,”

http://www.bls.gov/oes/oes_dl.htm, last accessed June 13, 2011.

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>, last 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=EC023114&-lang=en, last 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, 21 CFR parts 1, 7, and 16 are 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: January 27, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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