DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 14, and 17

[Docket No. FDA–2010–N–0560]

RIN 0910–AG55

Amendments to General Regulations of the Food and Drug Administration

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. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit either electronic or written comments by February 14, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0560 and/or RIN number 0910–AG55, by any of the following methods:

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 number and Regulatory Information Number (RIN) 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., rm. 240G, Rockville, MD 20850, 1–877–CTP–1373, *gerie.voss@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is this rule being issued as a companion proposed rule?

This proposed rule is a companion to the direct final rule regarding amendments to general regulations that is published in the final rules section of this issue of the **Federal Register**. The direct final rule and this companion proposed rule are identical. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comment and is withdrawn. We are publishing the direct final rule because the rule is noncontroversial, and we do not anticipate that it will receive any significant adverse comments. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document within 30 days after the comment period ends confirming when the direct final rule will go into effect.

If we receive any significant adverse comment regarding the direct final rule, we will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures under the Administrative Procedure Act (APA) (5 U.S.C. 553). The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with the APA. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

You can find additional information about FDA's direct final rulemaking procedures in the guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures" (62 FR 62466, November 21, 1997). This guidance document may be accessed at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.*

II. What is the background of the rule?

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 tobacco products. In order to effectuate these purposes, FDA is amending several provisions of its general regulations to reflect the Agency's new authority and mandate regarding tobacco products.

III. What does this companion proposed rule do?

FDA proposes to make the following amendments to its existing general regulations, reflecting the Agency's authority over tobacco products under the Tobacco Control Act:

1. Revising 21 CFR 1.1(b) to ensure the applicability of definitions contained in the Tobacco Control Act;
2. Removing the reference to "package" in 21 CFR 1.1(c), as this definition now also is covered by the Tobacco Control Act and is no longer provided solely by the Fair Packaging and Labeling Act;
3. Revising 21 CFR 1.20 to exclude from this definition of "package" the

term "package" as defined in section 900(13) of the Tobacco Control Act (21 U.S.C. 387q(13));

4. Adding paragraph (f) to 21 CFR 14.55 to identify the Tobacco Products Scientific Advisory Committee as a permanent statutory advisory committee; and

5. Adding paragraph (j) to 21 CFR 17.1 and revising 21 CFR 17.2 to reflect FDA's authority to impose civil monetary penalties on tobacco-related violations.

IV. What is the legal authority for this proposed rule?

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, 387, 387a, and 387q).

V. What is the environmental impact of this proposed rule?

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

VI. What is the economic impact of this proposed rule?

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 under 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 rule would not impose any new requirements on tobacco product manufacturers, retailers, or distributors, the Agency proposes to certify that the rule will not have a significant economic impact on a substantial number of small entities.

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.

VII. Paperwork Reduction Act of 1995

FDA concludes that the regulatory revisions and amendments identified 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.*).

VIII. What are the federalism impacts of this proposed rule?

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 has concluded 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.

IX. How do you submit comments on this proposed rule?

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.

List of Subjects

21 CFR Part 1

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

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 17

Administrative practice and procedure, Penalties.

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, 14, and 17 be amended to read 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. 1453, 1454, 1455; 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, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. In § 1.1 revise paragraph (b); and in the first sentence of paragraph (c), remove "*package* in § 1.20 and of" to read as follows:

§ 1.1 General.

* * * * *

(b) The definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act.

3. Amend § 1.20 by revising the introductory text to read as follows:

§ 1.20 Presence of mandatory label information.

Except as otherwise provided by section 900(13) of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387(13)) defining "package," the term *package* means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

* * * * *

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

4. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155

5. Amend § 14.55 by adding paragraph (f) to read as follows:

§ 14.55 Termination of advisory committees.

* * * * *

(f) The Tobacco Products Scientific Advisory Committee is a permanent statutory advisory committee established by section 917 of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387q) (Pub. L. 111–31) and is not subject to termination and renewal under paragraph (a) of this section.

PART 17—CIVIL MONEY PENALTIES HEARINGS

6. The authority citation for part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

7. Amend § 17.1 by adding paragraph (j) to read as follows:

§ 17.1 Scope.

* * * * *

(j) Section 303(f) of the act authorizing civil money penalties for any person who violates a requirement of the Family Smoking Prevention and Tobacco Control Act which relates to tobacco products.

8. Revise § 17.2 to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act.

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. section	Former maximum penalty amount (in dollars) [1]	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
		21 U.S.C.		
333(b)(2)(A)	55,000	For each of the first two violations in any 10-year period	2008	60,000.
333(b)(2)(B)	1,100,000	For each violation after the second conviction in any 10-year period.	2008	1,200,000.
333(b)(3)	110,000	Per violation	2008	120,000.
333(f)(1)(A)	16,500	Per violation	2008	16,500 (not adjusted).
333(f)(1)(A)	1,100,000	For the aggregate of violations	2008	1,200,000.
333(f)(2)(A)	55,000	Per individual	2008	60,000.
333(f)(2)(A)	275,000	Per "any other person"	2008	300,000.
333(f)(2)(A)	550,000	For all violations adjudicated in a single proceeding	2008	600,000.
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding	2007	10,000 (not adjusted).
333(f)(3)(B)	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected.	2007	10,000 (not adjusted).
333(f)(4)(A)(i)	250,000	Per violation	2007	250,000 (not adjusted).
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding	2007	1,000,000 (not adjusted).
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification.	2007	250,000 (not adjusted).
333(f)(4)(A)(ii)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day period.	2007	1,000,000 (not adjusted).
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding	2007	10,000,000 (not adjusted).
333(f)(9)(A)	[1] N/A	Per violation	2009	15,000 (not adjusted).
333(f)(9)(A)	N/A	For all violations adjudicated in a single proceeding	2009	1,000,000 (not adjusted).
333(f)(9)(B)(i)(I)	N/A	Per violation	2009	250,000 (not adjusted).
333(f)(9)(B)(i)(I)	N/A	For all violations adjudicated in a single proceeding	2009	1,000,000 (not adjusted).
333(f)(9)(B)(i)(II)	N/A	For the first 30-day period (or any portion thereof) of continued violation following notification.	2009	250,000 (not adjusted).
333(f)(9)(B)(i)(II)	N/A	For any 30-day period, where the amount doubled for every 30-day period of continued violation after the first 30-day period.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(i)(II)	N/A	For all violations adjudicated in a single proceeding	2009	10,000,000 (not adjusted).
333(f)(9)(B)(ii)(I)	N/A	Per violation	2009	250,000 (not adjusted).
333(f)(9)(B)(ii)(I)	N/A	For all violations adjudicated in a single proceeding	2009	1,000,000 (not adjusted).
333(f)(9)(B)(ii)(II)	N/A	For the first 30-day period (or any portion thereof) of continued violation following notification.	2009	250,000 (not adjusted).
333(f)(9)(B)(ii)(II)	N/A	For any 30-day period, where the amount doubled for every 30-day period of continued violation after the first 30-day period.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(ii)(II)	N/A	For all violations adjudicated in a single proceeding	2009	10,000,000 (not adjusted).
333(g)(1)	250,000	For the first violation in any 3-year period	2007	250,000 (not adjusted).
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2007	500,000 (not adjusted).
333 note	N/A	For the second violation (following a first violation with warning) within a 12-month period by a retailer with an approved training program.	2009	250 (not adjusted).
333 note	N/A	For the third violation within a 24-month period by a retailer with an approved training program.	2009	500 (not adjusted).
333 note	N/A	For the fourth violation within a 24-month period by a retailer with an approved training program.	2009	2,000 (not adjusted).
333 note	N/A	For the fifth violation within a 36-month period by a retailer with an approved training program.	2009	5,000 (not adjusted).

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. section	Former maximum penalty amount (in dollars) [1]	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
333 note	N/A	For the six or subsequent violation within a 48-month period by a retailer with an approved training program.	2009	10,000 (not adjusted).
333 note	N/A	For the first violation by a retailer without an approved training program.	2009	250 (not adjusted).
333 note	N/A	For the second violation within a 12-month period by a retailer without an approved training program.	2009	500 (not adjusted).
333 note	N/A	For the third violation within a 24-month period by a retailer without an approved training program.	2009	1,000 (not adjusted).
333 note	N/A	For the fourth violation within a 24-month period by a retailer without an approved training program.	2009	2,000 (not adjusted).
333 note	N/A	For the fifth violation within a 36-month period by a retailer without an approved training program.	2009	5,000 (not adjusted).
333 note	N/A	For the six or subsequent violation within a 48-month period by a retailer without an approved training program.	2009	10,000 (not adjusted).
335b(a)	275,000	Per violation for an individual	2008	300,000.
335b(a)	1,100,000	Per violation for "any other person"	2008	1,200,000.
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted).
360pp(b)(1)	330,000	For any related series of violations	2008	355,000.
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted).
300aa–28(b)(1)	110,000	Per occurrence	2008	120,000.

[1] Maximum penalties assessed under The Family Smoking Prevention and Tobacco Control Act do not have a "former maximum penalty."

Dated: November 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30040 Filed 11–29–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

RIN 1210–AB38

Target Date Disclosure

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Proposed regulation.

SUMMARY: The Department published in the **Federal Register** of October 24, 2007 a final regulation (the qualified default investment alternative regulation) providing relief from certain fiduciary responsibilities for fiduciaries of participant-directed individual account plans who, in the absence of directions from a participant, invest the participant's account in a qualified default investment alternative. On October 20, 2010, the Department published a final regulation that requires the disclosure of certain plan and investment-related information, including fee and expense information, to participants and beneficiaries in participant-directed individual account plans (the participant-level disclosure regulation). This document contains proposed amendments to the qualified default investment alternative regulation to provide more specificity as to the information that must be disclosed in the required notice to participants and beneficiaries concerning investments in qualified default investment alternatives, including target date or similar investments. This document also contains a proposed amendment to the participant-level disclosure regulation that would require the disclosure of the same information concerning target date or similar investments to all participants and beneficiaries in participant-directed individual account plans.

DATES: Written comments on the proposed regulation should be received by the Department of Labor no later than January 14, 2011.

ADDRESSES: To facilitate the receipt and processing of comments, EBSA encourages interested persons to submit their comments electronically to *e-ORI@dol.gov,* or by using the Federal eRulemaking portal *http://www.regulations.gov* (following instructions for submission of comments). Persons submitting comments electronically are encouraged not to submit paper copies. Persons interested in submitting comments on paper should send or deliver their comments (preferably three copies) to: Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Target Date Amendments. All comments will be available to the public, without charge, online at *http://www.regulations.gov* and *http://www.dol.gov/ebsa,* and at the Public Disclosure Room, Employee Benefits Security Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Kristen L. Zarenko, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

Section 624(a) of the Pension Protection Act of 2006 (Pension Protection Act) added a new section 404(c)(5) to ERISA. Section 404(c)(5)(A) of ERISA provides that, for purposes of