docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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.

Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12—(OMB Control Number 0910–0184)—Extension

The regulations in 21 CFR 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)), set forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d) (21 CFR 12.20(d)). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection for which a hearing has been requested must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
12.22	3	1	3	20	60

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on past filings. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order estimate approximately three requests are received by the Agency annually, with each requiring approximately 20 hours of preparation time.

Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23106 Filed 9–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0480]

Draft Guidance for Industry: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products.'' This draft guidance document is intended to assist persons submitting warning plans to FDA under the Comprehensive Smokeless Tobacco Health Education Act, as amended by the Family Smoking Prevention and Tobacco Control Act; and under the Federal Cigarette Labeling and Advertising Act, as amended by the Family Smoking Prevention and Tobacco Control Act, when that requirement takes effect.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 8, 2011.

Submit either electronic or written comments on the proposed collection of information by November 8, 2011.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance document entitled ''Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Gail Schmerfeld, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 1–877–287–1373, *gail.schmerfeld@fda.hhs.gov*.

With regard to the proposed collection of information: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft guidance entitled ''Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products.'' This guidance, when finalized, will provide industry with information on how to submit warning plans for smokeless tobacco products under section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act) and warning plans for cigarettes under section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) when that requirement takes effect.

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amended section 4 of FCLAA (15 U.S.C. 1333). When it takes effect, section 4 of FCLAA will require the submission of warning plans for cigarette packaging and advertising to FDA. Section 204 of the Tobacco Control Act amended section 3 of the Smokeless Tobacco Act (15 U.S.C. 4402), requiring the submission of warning plans for smokeless tobacco product packaging and advertising to FDA. The warning plans must be submitted by the tobacco product manufacturer, importer, distributor, or retailer, be approved by FDA, and provide for the random display of specified health warnings on packages and quarterly rotation of those health warnings in advertisements.

This draft guidance is intended to assist persons submitting warning plans for cigarettes and for smokeless tobacco products. The guidance discusses, among other things: The statutory requirement to submit a warning plan; definitions; who submits a warning plan; the scope of a warning plan; when to submit a warning plan; what information to include in a warning plan; where to submit; and what approval of a warning plan means.

II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA's good guidance practices regulations (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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.

Draft Guidance for Industry: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products (OMB Control Number 0910—New)

This draft guidance is intended to assist persons submitting warning plans for smokeless tobacco products under section 3 of the Smokeless Tobacco Act and for cigarettes under section 4 of FCLAA, when that requirement takes effect. The guidance document discusses, among other things: The statutory requirement to submit a warning plan; definitions; who submits a warning plan; the scope of a warning plan; when to submit a warning plan; what information should be submitted in a warning plan; where to submit a warning plan; and what approval of a warning plan means. FDA may collect statutorily mandated warning plan information for smokeless tobacco products under OMB control number 0910–0671. The purpose of the proposed information collection is to allow FDA to collect statutorily mandated information regarding warning plans for cigarettes and administrative information related to warning plans for both cigarettes and smokeless tobacco products.

Section 4 of FCLAA states that each cigarette package and advertisement must bear one of nine health warning statements and requires the submission of warning plans for cigarette packages and advertisements to FDA for review and approval. These requirements are currently not in effect. Section 4(d) of FCLAA (15 U.S.C. 1333(d)) requires FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany those warning statements. Section 201(b) of the Tobacco Control Act states that the requirements take effect 15 months after FDA issues these regulations. Under the provision, however, if a cigarette product was manufactured prior to the effective date of the final rule but its package does not contain a required warning, the product may be introduced into commerce in the United States within 30 days from such effective date. After the 30-day period,

manufacturers must not introduce into domestic commerce any cigarette the package of which does not contain a required warning (*i.e.,* a textual warning statement and accompanying graphic), irrespective of the date of manufacture. FDA published a proposed rule regarding these requirements on November 12, 2010 (see 75 FR 69524). FDA published the final rule on June 22, 2011 (see 76 FR 36628). This rule is effective September 22, 2012.

A. Warning Plans for Cigarettes

The requirement for submission of warning plans for cigarettes, and the specific requirements relating to the random display of required warnings on cigarette packaging and quarterly rotation of required warnings in cigarette advertising, appear at 15 U.S.C. 1333(c). In particular, warning plans for cigarette packaging must provide that all of the required warnings are randomly displayed in each 12-month period on each brand of the product; are randomly displayed in as equal a number of times as is possible on each brand of the product; and are randomly distributed in all areas of the United States in which the product is marketed. For FDA to approve it, a warning plan must provide for the required equal distribution and display of required warnings on packaging and must assure that all of the required warnings will be displayed by the manufacturer, importer, distributor, or retailer at the same time.

For FDA to approve it, a warning plan for cigarette advertising must provide that all of the required warnings are rotated quarterly in alternating sequence in advertisements for each brand of cigarettes.

Section 3 of the Smokeless Tobacco Act states that each smokeless tobacco product package and advertisement must bear one of four required warning statements and requires the submission of warning plans for smokeless tobacco product packages and advertisements to FDA for review and approval. The requirement for an FDA approved warning plan became effective June 22, 2010. On June 8, 2010, FDA announced by guidance its intent not to enforce the requirement that a brand of smokeless tobacco product must have an FDA-approved warning plan so long as a warning plan for the brand was submitted to FDA by July 22, 2010, and implemented (see 75 FR 32481). FDA expects to begin enforcing the requirement under Section 3 that there be an approved warning plan 6 months after the publication of the notice of availability of a final guidance on the ''Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products'' or 6 months after the publication of a final regulation regarding the submission of warning plans, whichever comes first.

B. Warning Plans for Smokeless Tobacco Products

The requirement for submission of warning plans for smokeless tobacco products, and the specific requirements relating to the random display of required warning statements on smokeless tobacco packaging and quarterly rotation of required warning statements in smokeless tobacco product advertising, appear at 15 U.S.C. 4402(b)(3). In particular, warning plans for smokeless tobacco product packaging must provide that all of the required warnings are randomly displayed in each 12-month period on each brand of the product; are randomly displayed in as equal a number of times as is possible on each brand of the product; and are randomly distributed in all areas of the United States in which the product is marketed. For FDA to approve it, a warning plan must provide for the required equal distribution and display of required warning statements on packaging and must assure that all of the required warning statements will be displayed by the manufacturer, importer, distributor, or retailer at the same time.

Warning plans for smokeless tobacco product advertising must provide that all of the required warning statements are rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product.

In an important change from prior law, outdoor billboard advertising for smokeless tobacco products must now include the required warning statements. Prior to its amendment by the Tobacco Control Act, the Smokeless Tobacco Act exempted outdoor billboard advertising from the requirement that smokeless tobacco product advertisements bear required warning statements, but the Tobacco Control Act amendments eliminated this exemption (which had been codified at 15 U.S.C. 4402(a)(2)). Thus, it is unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer to advertise or cause to be advertised within the United States a smokeless tobacco product on an outdoor billboard unless the advertisement bears one of the required warning statements.

Because section 9(1) of the Smokeless Tobacco Act, 15 U.S.C. 4408(1) (as amended by section 101(c) of the Tobacco Control Act), defines ''smokeless tobacco,'' by reference to section 900(18) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387(18)), as ''any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity,'' smokeless tobacco products intended to be placed in the nasal cavity must now comply with the warning requirements in section 3 of the Smokeless Tobacco Act. At this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that smokeless tobacco products marketed solely for use in the nasal cavity bear either the ''WARNING: This product can cause mouth cancer'' or the ''WARNING: This product can cause gum disease and tooth loss'' so long as a warning plan providing that packages and advertising for such products will bear the other two warnings has been submitted to FDA and implemented. FDA will give further consideration to the warnings smokeless tobacco products marketed solely for use in the nasal cavity should bear. FDA intends to provide further public notice prior to revising or rescinding this enforcement policy.

C. Description of Respondents

The respondents to this collection of information are manufacturers, importers, distributors, and retailers of cigarettes and/or smokeless tobacco products who are required to submit warning plans for cigarettes and smokeless tobacco products to FDA under FCLAA and the Smokeless Tobacco Act.

FDA estimates the burden of this collection of information as follows:

TABLE 1—CIGARETTE WARNING PLANS REPORTING BURDEN

[New Collection of Information]

Respondent by type of document	Number of respondents	Hours per response	Total burden hours
Cover Letter			
Manufacturers, Distributors, and Importers	226	5	1,130
Retailers	544	5	2,720
Total Cover Letters	770		3,850
Warning Plan			
Manufacturers, Distributors, and Importers	226	120	27,120
Retailers	544	120	65,280
Total Warning Plans	770		92,400
Total Burden Hours			96,250

TABLE 2—SMOKELESS TOBACCO PRODUCT WARNING PLANS REPORTING BURDEN

[New Cover Letter Plus Existing Collection of Information]

Respondent by type of document	Number of respondents	Hours per response	Total burden hours
Cover Letter			
Manufacturers, Distributors, and Importers	20	5	100
Retailers	10	5	50
Total Cover Letters	30		150
Warning Plan			
Manufacturers, Distributors, and Importers *			
Retailers	10	120	1,200
Total Warning Plans *	10		1,200
Total Burden Hours			1,350

*The burden for collection of the warning plans for Smokeless Tobacco Products from manufacturers, distributors, and importers is approved and covered under OMB control number 0910–0671.

FDA's estimate of the number of respondents in table 1 of this **Federal Register** document is based on the number of warning plans for cigarettes submitted to the Federal Trade Commission prior to the implementation of the Tobacco Control Act on June 22, 2009, which grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Using data from 34 State retailer lists, FDA identified 544 cigarette retailers who have 20 or more locations, and thus, may be more likely than smaller retailers to create their own advertisements and submit warning plans to FDA for those advertisements.

Thus, FDA estimates the number of manufacturers, importers, distributors, and retailers who are expected to submit warning plans for cigarette products in table 1 of this **Federal Register** document to be 770. Based on its experience, FDA estimates it may take between 2 and 8 hours to prepare and submit a cover letter, depending on the number of products and brands submitted. FDA estimates it could take 2 to 3 days for a person in a smaller firm to prepare warning plans, and up to a week for a person in a larger firm, depending on the number of products and brands submitted.

The burden hours for the preparation and submission of warning plans by manufacturers, distributors, and importers for smokeless tobacco products in table 2 of this document have already been approved by OMB under OMB control number 0910–0671. Based on plans submitted to FDA to date, we estimate the number of retailers who will submit warning plans for smokeless tobacco products to be 10. FDA estimates the burden hours for retailers to prepare warning plans to be 1,200. FDA estimates the additional burden hours for preparation of the cover letter is 150 hours (100 burden hours for manufacturers, distributors, and importers and 50 burden hours for retailers).

FDA estimates, therefore, that it will take an average of 5 hours to prepare and submit a cover letter and 120 hours to prepare and submit a warning plan for packaging and advertising. The total number of burden hours are estimated to be 1,350 hours ([150 cover letter burden hours] + [1,200 warning plan burden hours].)

IV. 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.

V. Electronic Access

Persons with access to the Internet may obtain an electronic version of this draft guidance document at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23099 Filed 9–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0376]

Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period by 60 days to December 2, 2011, for the notice entitled ''Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability,'' that appeared in the **Federal Register** of July 5, 2011 (76 FR 39111). In that document, FDA announced the availability of a draft guidance for industry and requested comments. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by December 2, 2011.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Corey Hilmas, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 5, 2011 (76 FR 39111), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry entitled ''Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.'' Comments on the draft guidance will assist FDA in the development of final guidance for industry on new dietary ingredient notifications and related issues.

The Agency has received a request for a 45-day extension of the comment period for this notice. FDA has considered the request and is extending the comment period for the notice entitled ''Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability,'' until December 2, 2011. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying action by the Agency.

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23098 Filed 9–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0147]

Draft Guidance for Industry and Food and Drug Administration Staff; Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.'' This draft guidance provides responses to questions FDA has received on the Family Smoking Prevention and Tobacco Control Act's (Tobacco Control Act) provisions on new tobacco products and substantial equivalence, including questions on changes to packaging and labeling. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 8, 2011.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

Submit written requests for single copies of the draft guidance document entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, *annette.marthaler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides responses to questions we have received on the Federal Food, Drug, and Cosmetic Act's (the FD&C Act) provisions on new tobacco products and