

(Response 1) FDA agrees with the comments.

(Comment 2) Reacting to FDA's declaration in the 60-day notice (77 FR 48988), that it intends to use "a mock snack product" to study nutrient content claims on fortified foods, one comment requested that FDA limit testing of such claims to sugars, cookies, candy, and carbonated beverages.

(Response 2) FDA agrees with the comment. FDA will limit testing of nutrient content claims on fortified

snack foods to mock cookies, candy, and carbonated beverages.

(Comment 3) One comment requested that FDA use images of actual commercially available labels for fortified snack products in the study instead of the proposed mock snack food labels, claiming that use of actual labels will increase the external validity of the studies.

(Response 3) FDA disagrees with the comment. Actual labels will increase the external validity of the findings but actual labels also are highly likely to

introduce brand effects, a bias that may be difficult to separate from effects of the claims themselves, which is the focus of the studies.

Recent study design decisions have indicated that the Agency needs a larger sample size for Study 1 than originally expected; therefore, the Agency will not conduct Study 2 (a shopping simulation study) which was described in the 60-day notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener .....	75	1	75	0.083 ..... (5 minutes)	6
Cognitive interview .....	9	1	9	1 hour ..... (60 minutes)	9
Pretest invitation .....	1,600	1	1,600	0.033 ..... (2 minutes)	53
Pretest .....	400	1	400	0.25 ..... (15 minutes)	100
Survey invitation .....	32,000	1	32,000	0.033 ..... (2 minutes)	1,056
Survey .....	7,500	1	7,500	0.25 ..... (15 minutes)	1,875
<b>Total</b> .....					<b>3,099</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration. Claims That Can Be Made for Conventional Foods and Dietary Supplements. September 2003. Available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm>.

2. Drichoutis, A.C., P. Lazaridis, and R.M. Nayga, "Consumers' Use of Nutritional Labels: A Review of Research Studies and Issues," *Academy of Marketing Science Review*, 2006(9), 2006. Available at <http://www.amsreview.org/articles/drichoutis09-2006.pdf>.

3. Lähteenmäki, L., P. Lampila, and K. Grunert, et al., "Impact of Health-Related Claims on the Perception of Other Product Attributes," *Food Policy*, 23: 230-239, 2010.

4. Labiner-Wolfe, J., C.-T. J. Lin, and L. Verrill, "Effect of Low Carbohydrate Claims

on Consumer Perceptions about Food Products' Healthfulness and Helpfulness for Weight Management," *Journal of Nutrition Education and Behavior*, 42(5): 315-320, 2010.

5. Roe, B., A.S. Levy, and B.M. Derby, "The Impact of Health Claims on Consumer Search and Product Evaluation Outcomes: Evidence from FDA Experimental Data," *Journal of Public Policy and Marketing*, 18(1): 89-105, 1999.

Dated: August 16, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0745]

**Request for Comments on the Food and Drug Administration Safety and Innovation Act Section 907 Report**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of a public docket for comments pertaining to the report issued as required by section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA). This notice is intended to solicit input from all relevant stakeholders before FDA issues an action plan to address issues raised in the report and to announce that such information submitted to FDA is available to all interested persons in a timely fashion.

**DATES:** Submit electronic or written comments by November 20, 2013.

**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:** Pamela E. Scott, Office of Women's Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2320, Silver Spring, MD 20903,

301-796-9441, [FDASIASECTION907@fda.hhs.gov](mailto:FDASIASECTION907@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On July 9, 2012, the President signed FDASIA (Pub. L. 112-144) into law. Section 907 of FDASIA requires that FDA report on and address certain information regarding clinical trial participation by demographic subgroups and subset analysis of the resulting data. Specifically, section 907(a) of FDASIA requires the Secretary of Health and Human Services (the Secretary), acting through the FDA Commissioner, to publish on FDA's Internet Web site a report "addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the FDA," and provide such publication to Congress. The report entitled "Reporting of Inclusion of Demographic Subgroups in Clinical Trials and Data Analysis in Applications for Drugs, Biologics, and Devices" is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentsToTheFDCAAct/FDASIA/ucm356316.htm>.

Section 907(b) of FDASIA further requires the Secretary, again acting through the Commissioner, to publish an action plan on the Internet Web site of FDA and provide such publication to Congress. The action plan is to contain recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness and in labeling; on the inclusion of such data, or the lack of availability of such data in labeling; and on ways to improve public availability of such data to patients, health care providers, and researchers. These recommendations are to include, as appropriate, a determination that distinguishes between product types and applicability. The action plan is due not later than 1 year after the publication of the report described previously.

FDA is opening a docket for 90 days to provide an opportunity for interested individuals to submit comments on the report for use in the development of the action plan. When submitting comments please reference the section of the report to which your comments pertain. This docket is intended to ensure that stakeholders have an opportunity to provide comments and that such information submitted to FDA is

available to all interested persons in a timely fashion.

##### II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 16, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2010-N-0277]

##### Guidance for Industry on Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." This guidance is intended to help small entities and other stakeholders comply with FDA's regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance 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.

Submit electronic comments on the 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.

##### FOR FURTHER INFORMATION CONTACT:

Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, [ctpcompliance@fda.hhs.gov](mailto:ctpcompliance@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31; 123 Stat. 1776) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and providing FDA with authority to regulate tobacco products. Section 102 of the Tobacco Control Act requires FDA to publish final regulations regarding cigarettes and smokeless tobacco which are identical in their provisions to the regulations issued by FDA on August 28, 1996 (61 FR 44396), with certain specified exceptions. In the **Federal Register** of March 19, 2010 (75 FR 13225), FDA published its final regulations entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," codified at 21 CFR part 1140. The final regulations apply to manufacturers, distributors, and retailers who manufacture, distribute, or sell cigarettes or smokeless tobacco products.

These regulations took effect on June 22, 2010, and impose restrictions on sales and distribution, including youth access, and advertising and labeling of cigarettes, including roll-your-own tobacco, cigarette tobacco, and smokeless tobacco. For instance, retailers are: Prohibited from selling cigarettes, including roll-your-own tobacco, cigarette tobacco, or smokeless tobacco to persons under the age of 18; required to verify the age of all customers under the age of 27 by checking a photographic identification that includes the bearer's date of birth; and prohibited from distributing free samples of cigarettes.

FDA announced the publication of a draft guidance document on this subject on June 9, 2010 (75 FR 32791), and issued a revised draft guidance on March 23, 2011 (76 FR 16424), to