

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.*

[FR Doc. 2013-20352 Filed 8-20-13; 11:15 am]

**BILLING CODE 4160-01-P**

#### 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

remove potential ambiguities and address several issues not included in the original draft guidance. In response to comments submitted to the public docket, at stakeholder meetings, and in calls from the public, FDA has provided additional clarifying examples to assist in complying with part 1140.

## II. Significance of Guidance

FDA is issuing this guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents." 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. 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>.

## IV. Electronic Access

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceCompliance/RegulatoryInformation/default.htm>.

Dated: August 19, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; 60-day Comment Request: NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI)

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**To Submit Comments and for Further Information:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: CAPT Michael Montello, Pharm. D., MBA, Cancer Therapy Evaluation Program, Operations and Informatics Branch, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number (240) 276-6080 or Email your request, including your address to: [mike.montello@nih.gov](mailto:mike.montello@nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**Comment Due Date:** Comments regarding this information collection are best assured of having their full effect if

received within 60 days of the date of this publication.

**Proposed Collection:** NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI), 0925-0625, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

**Need and Use of Information Collection:** The National Cancer Institute (NCI) Central Institutional Review Board (CIRB) provides a centralized approach to human subject protection and provides a cost efficient approach avoiding duplication of effort at each institution. The CIRB provides the services of a fully constituted IRB and provides a comprehensive and efficient mechanism to meet regulatory requirements pertaining to human subject protections including: Initial reviews, continuing reviews, review of amendments, and adverse events. The Initiative consists of three central IRBs: Adult CIRB—late phase emphasis, Adult CIRB—early phase emphasis, and Pediatric CIRB. CIRB membership includes oncology physicians, surgeons, nurses, patient advocates, ethicists, statisticians, pharmacists, attorneys and other health professionals. The benefits of the CIRB Initiative reaches research participants, investigators and research staff, Institutional Review Boards (IRB), and Institutions. Benefits include: Study participants having dedicated review of NCI-sponsored trials for participant protections, access to more trials more quickly and access to trials for rare diseases, accrual to trials begin more rapidly, ease of opening trials, elimination of need to submit study materials to local IRBs, and elimination of the need for a full board review. The benefits to the National Clinical Trials Network and Experimental Therapy-Clinical Trials Network include a cost efficient approach that avoids duplication of efforts at each institution. A variety of information collection tools are needed to support NCI's CIRB activities which include: Worksheets, forms and a survey that is provided to all customers contacting the CIRB helpdesk.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,199.