

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 5, 2013.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2013-02905 Filed 2-7-13; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0560]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 11, 2013.

**ADDRESSES:** To ensure that comments on the information collection are received,

OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0582. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—(OMB Control Number 0910-0582)—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket

submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812, Investigational Device Exemptions, under 21 CFR 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1, 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level 1 guidance document, entitled “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable,” issued under the Good Guidances Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of the guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one annual record, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours (700 × 4 = 2,800).

In the **Federal Register** of June 12, 2012 (77 FR 34954), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

Federal Food, Drug, and Cosmetic Act Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
520(g) (21 U.S.C. 360j(g)) .....	700	1	700	4	2,800

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

Dated: February 4, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-02858 Filed 2-7-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-1083]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; Civil Money Penalties for Tobacco Retailers: 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 a draft guidance for industry entitled “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.” This draft guidance provides responses to questions FDA has received regarding the issuance of civil money penalties for violations of regulations issued under the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to tobacco products in retail outlets. 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 on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft by April 9, 2013.

**ADDRESSES:** Submit written requests for single copies of the guidance entitled “Civil Money Penalties for Tobacco Retailers: 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 electronic access to the guidance document.

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.

#### **FOR FURTHER INFORMATION CONTACT:**

Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373, [gerie.voss@fda.hhs.gov](mailto:gerie.voss@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This draft guidance provides responses to questions FDA has received regarding the issuance of civil money penalties for violations of regulations issued under the FD&C Act relating to tobacco products in retail outlets. In this draft guidance, FDA provides responses to questions relating to civil money penalties for violations of the requirement that tobacco products may not be sold or distributed in violation of FDA’s “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” (75 FR 13225, March 19, 2010, codified at 21 CFR part 1140). This draft guidance also provides additional information regarding the complaint procedure used for civil money penalties.

##### **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.” 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 written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. 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 draft guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/Tobacco>

*Products/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: February 4, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-0077]

#### **Draft Guidance for Industry on Alzheimer’s Disease: Developing Drugs for the Treatment of Early Stage Disease; Availability**

**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 “Alzheimer’s Disease: Developing Drugs for the Treatment of Early Stage Disease.” This guidance outlines FDA’s current thinking as to how a sponsor could demonstrate efficacy in clinical trials in patients in the early stages of Alzheimer’s disease that occur before the onset of overt dementia.

**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 April 9, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

#### **FOR FURTHER INFORMATION CONTACT:**

Nicholas A. Kozauer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4351,