

PHASE 1.—FOCUS GROUP TESTING

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Annual total burden requested (in hours)
Rejected Screeners	152	1.0	1/60	2
Accepted Screeners	48	1.0	5/60	4
Parents	32	1.0	2.0	64
Teens	16	1.0	2.0	32
Total				102

PHASE 2.—PRE- AND POST-INTERVENTION PILOT CITY SURVEY TESTING

[based on two cities]

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated annual total burden hours requested
Screeners	1,777	2.0	1/60	59
Parents	600	2.0	15/60	300
Teens	200	2.0	15/60	100
Total				459

Dated: December 13, 2006.

Joan F. Karr,*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 2006N-0237]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications**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 January 19, 2007.**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: 202-395-6974.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.**Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—(OMB Control Number 0910-0523)—Extension**

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Public Law 101-629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any of the following combinations: (1) A drug and a device; (2) a device and a biological; (3) a biological and a drug; or

(4) a drug, a device, and a biological. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for classifying and determining which agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute. The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biologicals, and combination products. The respondents will be businesses or other for-profit organizations.

In the **Federal Register** of June 22, 2006 (71 FR 35916), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 3	43	1	43	24	1,032

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

Dated: December 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0202]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

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 January 19, 2007.

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: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285 (OMB Control Number 0910-0520)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(m)), which requires that FDA receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of FDA's regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting FDA review after an article of food has been refused admission under section 801(m)(1) of the act or placed under hold under section 801(l) of the act; and § 1.285(i) (21 CFR 1.285(i)) sets forth the procedure for post-hold submissions. Advance notice of imported food allows FDA, with the support of the Bureau of Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies.

Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA's regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS) (§ 1.280(a)(1)) or the FDA Prior Notice (PN) System Interface (Form FDA 3540) (§ 1.280(a)(2)). The term "Form FDA 3540" refers to the electronic system known as the FDA PN System Interface, which is available at <http://www.access.fda.gov>. Prior notice must be submitted electronically using either ABI/ACS or the FDA PN System Interface. Information collected by FDA in the prior notice submission includes: The submitter and transmitter (if

different from the submitter); entry type and CBP identifier; the article of food, including complete FDA product code; the manufacturer, for an article of food no longer in its natural state; the grower, if known, for an article of food that is in its natural state; the FDA Country of Production; the shipper, except for food imported by international mail; the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; the carrier and mode of transportation, except for food imported by international mail; and planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for FDA's importer's entry notice, which has been approved under OMB control number 0910-0046. The information in FDA's importer's entry notice is collected electronically via CBP's ABI/ACS at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in table 1 of this document reflects the reduced burden for prior notice submitted through ABI/ACS in the column labeled "Hours per Response."

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information if information changes after FDA has confirmed a prior notice submission for review (e.g., if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after FDA has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to 1.282(a)(1)(iii)). In the event that an article of food has been refused admission under section 801(m)(1) of the act or placed under