FDA will use the information from the proposed experimental study to evaluate regulatory policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this proposed experimental study will be used by the agency to assess likely consumer responses to various disclosure requirements for nutrient content claims.

In the **Federal Register** of February 6, 2006 (71 FR 6076), FDA published a 60–day notice requesting public comment on the information collection that will take place as part of the experimental study. FDA received one letter in response to the notice, containing multiple comments.

(*Comment 1*) One comment stated that the organization concurs with the objectives of the study and believes the information from this study will be useful to FDA in developing labeling policy to assist consumers with interpretation of *trans* fat claims in food labeling. Another comment suggested that FDA change the labels used to describe the three fatty acid profiles in the study (''good profile,'' ''medium profile,'' and ''poor profile'') because these descriptors were seen as overly negative. The comment recommended alternative language (''low profile,'' ''medium profile'' and ''high profile'') as a way to ensure that the products are not characterized as ''good foods'' or ''bad foods.''

(*Response*) This suggestion has been implemented. The terminology suggested in the comment adequately conveys the intended profile differences.

(*Comment 2*) One comment critiqued the draft Full Information treatment language. The comment criticized the one-page summary because it : (1) Did not identify calories in the discussion of fat as a major source of energy and (2) did not relate the calorie contribution of fat to that of carbohydrates and protein. The comment also criticized the information about sources of *trans* fat because it omitted mention of natural sources of *trans* fat in the diet, which the comment suggested would help ensure factually correct and balanced information about sources of *trans* in the diet. The comment questioned the value of stating that *trans* fat extends shelflife and has desirable taste characteristics since many saturated fat sources are relatively shelf stable and have desirable taste characteristics.

(*Response*) FDA agrees and has revised the Full Information treatment to incorporate these concerns. Calories and other sources of energy are now mentioned in the introductory passage. Natural sources of *trans* fat are now mentioned and the similarity between *trans* fat and saturated fat in terms of shelflife and taste are now addressed. The revised draft will be included in the study pretest and further revisions will be made if FDA determines they are needed based upon pretest results.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	40	1	40	.25	10
Study	2,880	1	2,880	.25	720
Total					730

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

Dated: December 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21317 Filed 12–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0197]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Food Facilities 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 16, 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.

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.230 through 1.235 (OMB Control Number 0910–0502)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 415 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. Sections 1.230 through 1.235 (21 CFR 1.230 through 1.235) set forth the procedures for registration of food facilities. Information provided to FDA under these regulations will help the agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply.

Description of respondents: The respondents to this information collection include owners, operators, or

agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States. Domestic facilities are required to register whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture/process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities are required to register.

FDA's regulations require that each facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States register with FDA using Form FDA 3537 (§ 1.231). The term ''Form FDA 3537'' refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at *http://www.access.fda.gov*. The agency strongly encourages electronic registration because it is faster and more convenient. The system the agency has developed can accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week, 365 days a year. A registering facility will receive confirmation of electronic registration and its registration number instantaneously once all the required fields on the registration screen are filled in. However, paper registrations will be accepted. Form FDA 3537 is available for download for registration by mail, fax, or CD–ROM. Registration by mail may take several weeks to several months, depending on the speed of the mail system and the number of paper registrations that FDA will have to enter manually.

Information FDA requires on the registration form includes the name and full address of the facility; emergency contact information; all trade names the facility uses; applicable food product categories identified in § 170.3 (21 CFR 170.3), unless ''most/all'' human food categories ''or none of the above mandatory categories'' is selected as a response; and a certification statement that includes the name of the individual authorized to submit the registration form. Additionally, facilities are encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under § 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is primarily a holding facility; and approximate dates of operation if the facility's business is seasonal.

In addition to registering, a facility is required to submit timely updates within 60 days of a change to any required information on its registration form, using Form FDA 3537 (§ 1.234), and to cancel its registration when the facility ceases to operate or is sold to new owners or ceases to manufacture/process, pack, or hold food for consumption in the United States, using Form FDA 3537a (§ 1.235).

In the **Federal Register** of June 2, 2006 (71 FR 32103), FDA published a 60-day notice requesting public comment on the information collection provisions. We received no comments.

FDA estimates the burden of complying with the information collection provisions of the agency's regulations for food facility registration as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
New Facilities						
Domestic						
1.230 through 1.233	FDA 3537[2]	13,650	1	13,650	2.5	34,125
Foreign						
1.230 through 1.233	FDA 3537	29,200	1	29,200	8.5	248,200
New Facility Registration Subtotal						282,325
Previously Registered Facilities-Updates (Form 3537) and Cancellations (Form 3537a)						
1.234	FDA 3537	92,850	1	92,850	1	92,850
1.235	FDA 3537a	1,300	1	1,300	1	1,300
Updates or Cancellations to Existing Registration Subtotal						94,150
Total Hours Annually						376,475

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term ''Form FDA 3537'' refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at *http://www.access.fda.gov*.

This estimate is based on FDA's experience and the average number of new facility registrations, updates and cancellations received in the past 3 years. FDA received 82,485 new domestic facility registrations during 2003; 32,099 during 2004; and 13,652 during 2005. Based on this experience, FDA estimates the annual number of new domestic facility registrations will be 13,650. FDA estimates that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the agency's registration regulations will require a burden of approximately 2.5 hours per average domestic facility registration. The average domestic facility burden hour estimate of 2.5 hours takes into account that some respondents completing the registration may not have readily available Internet access. Thus, the total annual burden for new domestic facility registrations is

estimated to be 34,125 hours (13,650 x 2.5 hours).

FDA received 89,990 new foreign facility registrations during 2003; 49,574 during 2004; and 29,193 during 2005. Based on this experience, FDA estimates the annual number of new foreign facility registrations will be 29,200. FDA estimates that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the agency's registration regulations will require a burden of approximately 8.5 hours per average foreign facility registration. The average foreign facility burden hour estimate of 8.5 hours includes an estimate of the additional burden on a foreign facility to obtain a U.S. agent, and takes into account that for some foreign facilities the respondent completing the registration may not be fluent in English and/or not have readily available Internet access. Thus, the total annual burden for new foreign facility registrations is estimated to be 248,200 hours (29,200 x 8.5 hours).

FDA received 131,354 updates to facility registrations during 2003; 137,384 during 2004; and 92,835 during 2005. Based on this experience, FDA estimates that it will receive 92,850 updates annually. FDA also estimates that updating a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. Thus, the total annual burden for updating all registrations is estimated to be 92,850 hours.

FDA received 12,556 cancellations of facility registrations during 2003; 7,467 during 2004; and 1,280 during 2005. Based on this experience, FDA estimates the annual number of cancellations will be 1,300. FDA also estimates that cancelling a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. Thus, the total annual burden for cancelling registrations is estimated to be 1,300 hours.

In cases where a regulation implements a statutory information collection requirement, only the additional burden attributable to the regulation, if any, has been included in FDA's burden estimate.

Dated: December 11, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21375 Filed 12–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0476]

Drug Products Containing Quinine; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to take enforcement action against unapproved drug products containing quinine (including quinine sulfate and any other salt of quinine) and persons who cause the manufacture of such products or their shipment in interstate commerce. Drug products containing quinine, quinine sulfate, and any other salt of quinine are new drugs that require approved applications. One firm has an approved application to market a drug product containing quinine sulfate to treat malaria; this product has been designated an orphan drug product. Other manufacturers who wish to market a drug product containing quinine, quinine sulfate, or any other salt of quinine must obtain FDA approval of a new drug application (NDA) or an abbreviated new drug application (ANDA); consideration of any such applications will be subject to the rights of the current NDA holder under the Orphan Drug Act.

DATES: This notice is effective December 15, 2006.

For marketed, unapproved drug products containing quinine, quinine sulfate, or any salt of quinine that have a National Drug Code (NDC) number that is listed with FDA on the effective date of this notice (i.e., ''currently marketed products''), however, the agency intends to exercise its enforcement discretion to permit products marketed with those NDC numbers a brief period of continued marketing after December 15, 2006 as follows. Any firm manufacturing such an unapproved product may not manufacture that product on or after February 13, 2007. Any firm distributing such an unapproved product may not ship the product in interstate commerce on or after June 13, 2007. Unapproved drug products containing quinine, quinine sulfate, or any salt of quinine that are not currently marketed products on the effective date of this notice must, as of the effective date of this notice, have approved applications prior to their shipment in interstate commerce. Submission of an application does not excuse timely compliance with this notice.

ADDRESSES: All communications in response to this notice should be identified with Docket No. 2006N–0476 and directed to the appropriate office listed as follows:

Regarding applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)): Division of Special Pathogen and Transplant Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002.

Regarding applications under section 505(j) of the act: Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855.

All other communications: John Loh, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John Loh, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8965, e-mail: *john.loh@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Quinine is the chief alkaloid of cinchona, the bark of the cinchona tree indigenous to parts of South America. Recorded medical use of cinchona dates back to the 17th century. Quinine was first isolated from cinchona in 1820. Quinine (the term ''quinine'' as used in this notice refers to quinine, quinine sulfate, and other quinine salts) has been used to treat malaria since the 19th century. It was used extensively for mass prophylaxis in malaria control programs in the early 20th century. As more predictable and effective synthetic antimalarial drugs began to be developed in the 1930s, the use of quinine to treat and/or prevent malaria declined. However, with the increasing resistance of the malaria parasite to some of these synthetic malarial treatments, quinine is again emerging as an important treatment for malaria.

Quinine also has been used for the treatment and/or prevention of nocturnal leg muscle cramps, similar conditions such as a restless leg syndrome, and, very rarely, a number of other conditions, including Babesiosis (another parasitic infection) and certain myotonic disorders. The predominant