New Dietary Ingredient Premarket Notification—21 CFR 190.6 (OMB Control Number 0910–0330—Extension)

Description: Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides for the notification of the Secretary of Health and Human Services (the Secretary) (and by delegation FDA) at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient.

The agency established 21 CFR 190.6 as the procedural regulation for this program. This regulation provides details of the administrative procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 413(a) of the act and to show the basis on which a manufacturer or distributor of a new dietary ingredient or a dietary supplement containing a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

Description of Respondents: Businesses or other for-profit organizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	11	1	11	20	220

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

The agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the agency is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the act, will require a burden of approximately 20 hours of work per submission. This estimate is based on the average number of premarket notifications received by the agency in the last 3 years.

Dated: February 1, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–3014 Filed 2–8–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0394]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Investigational Device Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Investigational Device Exemptions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 23, 1998 (63 FR 64617), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–391. The approval expires on January 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: February 2, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–3016 Filed 2–8–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0698]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Survey of Consumer Attitudes Toward Potential Changes in Food Standards of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by March 11, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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

Survey of Consumer Attitudes Toward Potential Changes in Food Standards of Identity

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. FDA is planning to conduct a telephone-mail-telephone consumer survey about consumer attitudes towards potential changes in food standards of identity under this authority. A nationally representative sample of 600 adults, who regularly do the food shopping for their households, will be selected at random and asked if they would agree to complete a mail survey. Participation will be voluntary. Detailed information will be obtained about how consumers would be affected by changes to standards and what their preferences are for retaining, revising, or eliminating standards. FDA is reviewing standard of identity regulations for foods in order to determine which elements of those regulations are most important to fulfilling the goals of those regulations. The information to be collected will address consumer attitudes toward potential changes in the standards of identity for particular products. The products will be chosen to represent general categories of products that share theoretically relevant characteristics. The changes will be chosen to represent general types of changes that might be made to standards of identity. Therefore, the information collected on particular changes in the standards of identity for particular products should provide information that can be generalized to other changes and other products. The information collected will be used to shape FDA's policy on revising standards of identity.

In the **Federal Register** of September 3, 1998 (63 FR 47031), the agency requested comments on the proposed collection of information. FDA received five comments. One comment noted that Table 1 in the September 3, 1998, notice appeared to contain a typographical error. According to this comment, the ''0.8'' in the ''Hours per Response'' column for receiving the initial recruiting telephone call should be ''0.08'' if that number is to be consistent with the other numbers in that table. FDA agrees with this comment and has revised the estimate for the initial telephone call accordingly.

Some comments argued the proposed survey is unnecessary because industry groups have already indicated how they believe FDA should revise the standards of identity governing their products. FDA values the input of industry and intends to give full consideration to industry recommendations on revising standards. However, the primary purpose of standards of identity is to assist consumers. Therefore, FDA believes that information on consumer attitudes toward revising standards is also relevant to revising standards.

Some comments suggested that the proposed survey is unnecessary because similar surveys have already been done by industry groups and the results of those surveys have already been shared with FDA. According to these comments, FDA already has sufficient information on consumer attitudes toward revising standards of identity to proceed with the task of reviewing and revising standards. Although the surveys that have been performed by industry groups contain much information that is relevant to revising standards, FDA disagrees that gathering additional information is unnecessary. One of the issues on which FDA believes that additional information is necessary is consumer attitudes toward the tradeoffs involved in revising various types of standards of identity in various ways. FDA believes that this issue has not been adequately addressed in the surveys that have been performed by industry groups.

Many comments suggested that the proposed survey will be too general to have any practical utility for revising standards of identity. According to these comments, survey results on consumer attitudes on changing any given standard will not be relevant to the determining consumer attitudes toward changing any other standard. These comments suggested that the surveys that have been performed by industry groups do not suffer from this drawback because they deal with particular products. FDA acknowledges the difficulties involved in extrapolating the results of consumer attitudes across different standards and products. However, FDA believes that standards and products can be grouped in a meaningful way and that the results of consumer attitudes toward a particular change in the standard governing a particular product will be related to consumer attitudes toward similar changes in the standards governing other products of that type. FDA agrees that it would be more straightforward to do a separate survey on every possible change in every standard. However, FDA has insufficient resources to implement such an approach. As indicated previously, FDA agrees that the surveys performed by industry groups on particular products contain much information that is relevant to revising those standards. However, FDA does not believe that those surveys provide all the information that is relevant to revising those standards.

Other comments suggested that the proposed survey will have no practical utility because consumer attitudes toward the hypothetical changes to standards discussed in the survey will not be relevant to determining consumer attitudes toward the types of changes that FDA would actually make to standards. FDA disagrees with this comment. The types of changes discussed in the proposed survey will reflect the types of changes that FDA might actually make.

Some comments argued that the proposed survey is fundamentally misguided because consumers are not generally familiar with standards of identity and will not be able to respond to questions concerning changes in standards of identity. FDA is aware that most consumers are not already familiar with standards. The survey will be written in such a manner that consumers are provided with the information they need to consider changes to standards.

Finally, some comments noted that interpreting the results of consumer surveys is complicated because those results depend crucially on what questions are asked and on how those questions are asked. These comments noted that industry has considerable experience conducting consumer surveys and recommended that FDA elicit the input of industry experts when designing the survey instrument. FDA is aware of the issues that are involved in interpreting the results of consumer surveys and believes that it has access to sufficient technical expertise to conduct consumer surveys without the assistance of industry experts. In addition, FDA notes that it does not intend to revise standards based only on the results of this particular survey, but intends to also take into account the results of all other relevant surveys, including those sponsored by industry groups, and all other relevant information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Receive initial recruiting telephone call	600	1	600	0.08	48
Read instructions and complete mail survey	600	1	600	0.59	354
Complete followup telephone interview	600	1	600	0.08	48
Total					450

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

The burden estimate is based on two rounds of focus groups conducted to test the survey instrument. The estimates for the length of the initial and followup interviews are based on similar studies that have been conducted.

Dated: January 31, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–3015 Filed 2–8–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Allergenic Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 22, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) The current organization and the research programs of the Laboratory of Immunobiochemistry, Division of Allergenic Products and Parasitology, Office of Vaccines Research and Review; (2) regulatory proposals concerning the potency limits for standardized allergen vaccines and the requirements for protein content of these vaccines; (3) modifications of the competitive ELISA assay; (4) proposed package insert for allergen extracts; (5) issues regarding use of pure allergens versus U.S. standards; and (6) an update on the status of class IIIA allergen extracts.

Procedure: On February 22, 1999, from 8 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 16, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 16, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 22, 1999, from 3 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding applications under FDA review.

FDA regrets that it was unable to publish this notice 15 days prior to the February 22, 1999, Allergenic Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Allergenic Products Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 3, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–3149 Filed 2–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 4, 1999, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Rhonda W. Stover, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application 20–930, pexiganan acetate 1 percent topical cream (Magainin Pharmaceuticals) for treatment of infections in diabetic foot ulcers.