This is a one-time survey. The burden estimate is based on FDA's experience with conducting similar surveys.

Dated: May 15, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–12854 Filed 5–22–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacological 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: Psychopharmacological 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 July 19, 2000, 8 a.m. to 5 p.m.

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

Contact Person: Sandra L. Titus or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093) Rockville, MD 20857, 301–827–7001, or e-mail Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the safety and efficacy of new drug application (NDA) 20–825, Zeldox™ (ziprasidone hydrochloride capsules, Pfizer, Inc.), proposed for the management of psychotic disorders.

Procedure: 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 July 17, 2000. Oral presentations from the public will be scheduled on July 19, 2000, between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 17, 2000, 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.

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

Dated: May 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–12855 Filed 5–22–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–00–2000]

Memorandum of Understanding Between the Food and Drug Administration, U.S. Department of Health and Human Services, and the Food Safety and Inspection Service, U.S. Department of Agriculture, Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Food Safety and Inspection Service, U.S. Department of Agriculture (FSIS). The purpose of the agreement is to establish the working relationship to be followed by FDA and FSIS in responding to requests for the sanctioning of the use of food ingredients and sources of radiation subject to regulation by FDA and intended for use in the production of meat and meat food products.

DATES: The agreement became effective January 31, 2000.

FOR FURTHER INFORMATION CONTACT: Arletta M. Beloian, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3082.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: May 16, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

The MOU is set forth in its entirety as follows:

BILLING CODE 4160–01–F

FDA # 225-00-2000

MEMORANDUM OF UNDERSTANDING

Between The

FOOD SAFETY AND INSPECTION SERVICE
UNITED STATES DEPARTMENT OF AGRICULTURE

And The

FOOD AND DRUG ADMINISTRATION
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products

I. PURPOSE

This agreement establishes the working relationship to be followed by FSIS and FDA in responding to requests for the sanctioning of the use of food ingredients and sources of radiation subject to regulation by the FDA and intended for use in the production of meat and meat food products (hereinafter known collectively as meat products) and poultry products regulated by FSIS.

II. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FFDCA) provides FDA with the authority to determine the safety, wholesomeness, and accurate labeling of food. The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) provide FSIS with the authority to regulate establishments that process meat and poultry, and determine the safety, wholesomeness, and accurate labeling of such meat and poultry products.

Section 409 of the FFDCA (21 U.S.C. 348) requires premarket approval of food additives that are not food contact substances. Under section 409, any person may submit to FDA a food additive petition that includes data and information that the petitioner believes establish that use of the substance is safe under its intended conditions of use, (i.e., that there is reasonable certainty that the substance is not harmful under the intended conditions of use (21 CFR 170.3(i)). If, based on the data and information in the petition, FDA finds that the food additive is safe under the conditions of its intended use, FDA promulgates a regulation specifying the conditions under which the additive may be safely used.

Likewise, section 721 of the FFDCA (21 U.S.C. 379e) requires premarket review and listing of color additives. Under section 721, any person may submit to FDA a color additive petition that includes data and information that the petitioner believes establish that the intended use of the substance is safe, and that the color additive is suitable for its intended use. If, based on the data and information in the petition, FDA finds that the color additive is suitable and safe under the conditions of its intended use, FDA promulgates a regulation specifying the conditions under which the color additive may be safely used.

In enacting Section 409, Congress recognized that many substances intentionally added to foods would not require a formal premarket review by FDA to ensure their safety, either because their safety had been established by a long history of safe use in food or by virtue of the nature of the substance, its customary or projected conditions of use, and the information generally available to scientists about the substance. Congress thus adopted a two-step definition of "food additive" (21 U.S.C. 321(s)). The first step broadly includes any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food. The second step, however, excludes from the definition of food additive substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety, as having been adequately shown to be safe under the conditions of their intended use. It is on the basis of this generally recognized as safe (GRAS) provision in the food additive definition that many food ingredients are marketed without formal FDA review and approval. However, there is no corresponding GRAS provision for color additives.

The FMIA and the PPIA grant FSIS the authority to regulate the use of GRAS substances, FDA-listed food and color additives, and sources of radiation to ensure that their use does not adulterate meat or poultry products. Under the tenets of the FMIA and PPIA, and their implementing regulations, FSIS determines the suitability (i.e., status) of the use of food ingredients and sources of radiation used in the production of meat and poultry products, in accordance with various FSIS regulations and policies.

III. SCOPE

This is a collaborative FSIS-FDA agreement regarding food ingredients and sources of radiation intended for use in the production of meat and poultry products. This agreement between FSIS and FDA covers the following circumstances: (1) when a party requests Federal approval of a food ingredient or source of radiation that specifies use in or on a meat or poultry product; (2) when a party requests Federal approval of a food ingredient or source of radiation that is intended for use in or on food generally, but does not specify whether it is intended for use in or on a meat and poultry product; (3) when a party requests a suitability determination regarding the use of a food ingredient or source of radiation in or on a meat or poultry product; and (4) when a party inquires about the use of a food ingredient or source of radiation used in or on a meat or poultry product.

IV. COLLABORATIVE FSIS-FDA AGREEMENT REGARDING FOOD INGREDIENTS AND SOURCES OF RADIATION INTENDED FOR USE IN THE PRODUCTION OF MEAT AND POULTRY PRODUCTS

FSIS and FDA agree to cooperate and collaborate on the review of submissions each agency receives regarding the use of food ingredients and sources of radiation used in the production of meat or poultry products. The agencies further agree that the details of that cooperative relationship are to be elaborated on in a set of mutually agreeable standard operating procedures. The standard operating procedures will provide consistency in the processing of the relevant submissions regardless of which agency is the receiving agency or which agency the consulting agency. When appropriate, the consulting agency to this agreement will provide its evaluation on relevant parts of submissions to the other agency in writing.

V. IMPLEMENTATION OF THE AGREEMENT

FSIS and FDA jointly agree:

1. That the officials of the two agencies responsible for implementing the agreement are:

   At FSIS: Director, Labeling and Additives Policy Division (or other FSIS designee).

   At FDA: Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition

2. That written notice will be provided to the Director of the Center for Food Safety and Applied Nutrition, FDA, and to the Administrator of the Food Safety and Inspection Service, USDA, of any rulemaking initiative not in keeping with the

provisions of this MOU or about which there is an interagency disagreement, prior to public announcement of the rulemaking.

3. That the Administrator of FSIS and Director of CFSAN shall resolve any problems and make decisions by consensus in areas of disagreement.

VI. OTHER AGREEMENTS

The provisions of this MOU are not intended to add to or detract from any of the authorities provided to either FDA or FSIS by the FFDCA, FMIA, or PPIA, or the regulations promulgated by each agency under such authorities. Each agency reserves the authority to review, independently of the other, matters of concern to their respective authorities.

VII. DURATION OF MOU

This agreement becomes effective upon acceptance by both agencies and will continue indefinitely. It may be modified by mutual written consent or terminated by either agency with a 30-day written notice to the other agency.

Signed:

By: _____

Title: Administrator, FSIS

Date: Jan. 31, 2000

Signed:

By: _____

Title: Senior Associate Commissioner for Policy, Planning and Legislation, FDA

Date: January 18, 2000

[FR Doc. 00–12853 Filed 5–22–00; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouse Customer Satisfaction Survey

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects; the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management (OMB) for review and approval.

Title: NIDDK Information Clearinghouses Customer Satisfaction Survey.

NIDDK will conduct a survey to evaluate the efficiency and effectiveness of services provided NIDDK's three information clearinghouses: National Diabetes Information Clearinghouse, National Digestive Diseases Information Clearinghouse, National Kidney and Urologic Diseases Information Clearinghouse. The survey responds to Executive Order 12862, ''Setting Customer Service Standards,'' which requires agencies and departments to identify and survey their ''customers to determine the kind and quality of service they want and their level of satisfaction with existing service.''

Frequency of Response: On occasion.

Affected Public: Individuals or households; clinics or doctor's offices.

Type of Respondents: Physicians, nurses, patients, family.