

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690-6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: August 27, 1997.

William R. Beldon,

Acting Deputy Assistant Secretary, Budget.

[FR Doc. 97-23304 Filed 9-2-97; 8:45 am]

BILLING CODE 4150-04-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Two Meetings of the National Bioethics Advisory Commission (NBAC): One Each of its Genetics and Human Subjects Subcommittees

SUMMARY: Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given of two meetings of the National Bioethics Advisory Commission. Commission members will solicit testimony on the protection of the rights and welfare of human subjects in research including decisionally and/or cognitively impaired populations and will address the use of genetic information involved in tissue storage. The meetings are open to the public and opportunities for statements by the public will be provided.

DATES/TIMES/LOCATIONS:

Human Subjects Subcommittee

September 18, 1997, 8:15 am-5:30 pm, (9:00 am-12 noon public hearing)—National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 10, Bethesda, Maryland 20892

Genetics Subcommittee

September 18, 1997, 3:00 pm-5:30 pm—National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 9, Bethesda, Maryland 20892

September 19, 1997, 8:30 am-12:30 pm—Same Location as Above

SUPPLEMENTARY INFORMATION: The President established the National Bioethics Advisory Commission (NBAC) by Executive Order 12975 on October 3, 1995. The mission of the NBAC is to advise and make recommendations to the National Science and Technology Council and other entities on bioethical issues arising from the research on human biology and behavior, and in the applications of that research including clinical applications.

Public Participation

All meetings are open to the public with attendance limited by the availability of space. On September 18, 1997, the Human Subjects Subcommittee of the National Bioethics Advisory Commission will discuss possible guidelines for research involving decisionally or cognitively impaired subjects, and public testimony is invited on the ethical issues of such research. A public hearing will be held on ethical issues in research involving decisionally or cognitively impaired individuals from 9:00 am-12 noon on September 18, 1997. Members of the public who wish to present oral statements should contact the Deputy Executive Director of the NBAC by telephone, fax machine, or mail as shown below prior to the meeting as soon as possible. Individuals unable to make oral presentations are encouraged to mail or fax their comments to the NBAC staff office for distribution to the subcommittee members or Commission and inclusion in the public record.

Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact NBAC staff at the address or telephone number listed below as soon as possible.

FOR FURTHER INFORMATION CONTACT: Ms. Henrietta D. Hyatt-Knorr, National Bioethics Advisory Commission, MSC-7508, 6100 Executive Boulevard, Suite 5B01, Rockville, Maryland 20892-7508, telephone 301-402-4242, fax number 301-480-6900.

Dated: August 28, 1997.

Henrietta D. Hyatt-Knorr,

Deputy Executive Director, Acting, National Bioethics Advisory Commission.

[FR Doc. 97-23377 Filed 9-2-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0353]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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 October 3, 1997.

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

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, 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 section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Food Additives and Food Additive Petitions (21 CFR Parts 171, 172, 173, 175 to 178, and 180) (OMB Control Number 0910-0016—Reinstatement)

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that any particular use or intended use of a food additive shall be deemed to be unsafe, unless the additive and its use or intended use are in conformity with a regulation issued under section 409 of the act that describes the condition(s) under which the additive may be safely used, or unless the additive and its use or intended use conform to the terms of an exemption for investigational use. Food additive petitions are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 (21 CFR 171.1)

specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 175 to 178, and 180 (21 CFR parts 172, 173, 175 to 178, and 180) contain labeling requirements for certain food additives to ensure their safe use.

FDA scientific personnel review food additive petitions to ensure the safety of the intended use of the food additive in or on food, or of a food additive that may be present in food as a result of its use in articles that contact food. FDA requires food additive petitions to contain the information specified in § 171.1 in order to determine whether a petitioned use for a food additive is safe, as required by the act. This regulation

(§ 171.1) implements section 409(b)(2) of the act.

Respondents are businesses engaged in the manufacture or sale of food, food ingredients, or substances used in materials that come into contact with food.

FDA estimates the burden of complying with the information collection provisions of the agency's food additive petition regulations as follows:

TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
171.1	44	1	44	2,876	126,560
Part 172	44	1	44	0	0
Part 173	44	1	44	0	0
Parts 175 to 178	44	1	44	0	0
Part 180	44	1	44	0	0
Total	44				126,560

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

This estimate is based on the average number of new food additive petitions received in fiscal year 1995 and the total hours expended by petitioners to prepare the petitions. The burden varies with the complexity of the petition submitted, because food additive petitions involve the analysis of scientific data and information, as well as the work of assembling the petition itself. Because labeling requirements under parts 172, 173, 175 to 178, and 180 for particular food additives involve information required as part of the food additive petition safety review process under § 171.1, the estimate for the number of respondents is the same and the burden hours for labeling are included in the estimate for § 171.1.

Dated: August 26, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97-23246 Filed 9-2-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E-0145]

Determination of Regulatory Review Period for Purposes of Patent Extension; PRELAY™ and REZULIN™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for

PRELAY™ and REZULIN™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.
FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes

effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug products PRELAY™ and REZULIN™ (troglitazone). PRELAY™ and REZULIN™ are indicated for use in patients with type II diabetes currently on insulin therapy whose hyperglycemia is inadequately controlled ($HbA_{1c} > 8.5\%$) despite insulin therapy of over 30 units per day given as multiple injections. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PRELAY™ and REZULIN™ (U.S. Patent No. 4,572,912) from Sankyo Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 21, 1997, FDA advised the Patent and Trademark