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 Commissione for Policy.*

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

**BILLING CODE 4160–01–F**

## 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

Office that these human drug products had undergone a regulatory review period and that the approvals of PRELAY™ and REZULIN™ represented the first permitted commercial marketing or use of the products. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PRELAY™ and REZULIN™ is 2,885 days. Of this time, 2,703 days occurred during the testing phase of the regulatory review period, while 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: March 9, 1989. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on March 9, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: August 1, 1996. The applicant claims July 31, 1996, as the date the New Drug Applications (NDA's) for PRELAY™ (NDA 20–719) and REZULIN™ (NDA 20–720) were initially submitted. However, FDA records indicate that NDA's 20–719 and 20–720 were submitted on August 1, 1996.

3. *The date the application was approved*: January 29, 1997. FDA has verified the applicant's claim that NDA's 20–719 and 20–720 were approved on January 29, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,534 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before November 3, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before March 2, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 24, 1997.

**Allen B. Duncan,**

*Acting Associate Commissioner for Health Affairs.*

[FR Doc. 97–23244 Filed 9–2–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Open Meeting for Representatives of Health Professional Organizations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an open meeting with representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. This meeting will provide participants an opportunity to hear a discussion on the Food Safety Initiative and reducing food-borne illness.

**DATES:** The meeting will be held on Monday, October 6, 1997, from 1:30 p.m. to 3:30 p.m.

**ADDRESSES:** The meeting will be held at the Bethesda Holiday Inn, 8210 Wisconsin Ave., Bethesda, MD. Interested persons may register with Betty Palsgrove at 301–443–1652. Registrations also may be transmitted by FAX to 1–800–344–3332 or 301–443–2446.

**FOR FURTHER INFORMATION CONTACT:** Peter H. Rheinstein, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5470.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff as well as representatives from the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). It will also provide an opportunity for informal discussion on the role of the Federal Government and health professional organizations in reducing food-borne illness in general, as well as identifying and treating the illness in patients.

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received and should be sent to the contact person listed above. Registration should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: August 27, 1997.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 97–23299 Filed 9–2–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Proposed Review Criterion for Grants for Primary Care Training Programs for Fiscal Year 1998

Grants for Primary Care Training programs are authorized under sections 747 (a) and (b), 748, 750 and 751, title VII of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102–408, dated October 13, 1992. These grant programs include:

Grants for Predoctoral Training in Family Medicine
Grants for Faculty Development in Family Medicine
Grants for Graduate Training in Family Medicine
Grants for Establishment of Departments of Family Medicine
Grants for Residency Training in General Internal Medicine and General Pediatrics
Grants for Faculty Development in General Internal Medicine and General Pediatrics
Grants for Physician Assistant Training
Grants for Podiatric Primary Care Residency Training

#### Proposed Review Criterion

The following criterion is proposed to be added to the existing review criteria established in 61 FR 52034 on October 4, 1996:

''5. Project impact/influence in shaping the curriculum, program, department, institution and the community.''