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.''