tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is typically a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

There are no NDAs for acetaminophen and codeine phosphate tablets. The initial acetaminophen/codeine combination drug product was accepted as an ANDA based on a **Federal Register** notice finding TRIGESIC with codeine to be effective for the relief of mild to moderate pain. (See 38 FR 3210, February 2, 1973.) FDA made this effectiveness determination under the 1962 amendments to the act, which required a demonstration of the effectiveness of new drugs, including those approved prior to 1962. FDA contracted with the National Academy of Science/National Research Council to carry out the Drug Efficacy Study assessing the evidence of effectiveness available for new drugs approved prior to 1962. TRIGESIC with codeine contained codeine, acetaminophen, aspirin, and caffeine. The initial ANDA for acetaminophen and codeine tablets was considered to be similar and related to TRIGESIC with codeine tablets, and therefore was accepted as an ANDA.

Roxane Laboratories (Roxane) filed a suitability petition (86P–0161/CP) on April 14, 1986, requesting permission to file ANDAs for three different strengths of acetaminophen and codeine phosphate tablets. Its suitability petition was approved on May 8, 1986. Roxane's acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, are the subject of ANDAs 89–511, 89–512, and 89–513, respectively. FDA approved ANDAs 89–511, 89–512, and 89–513, held by Roxane, on April 24, 1989, at which time they became ''listed drugs'' within the meaning of 21 CFR 314.3. On October 23, 1997, Roxane requested withdrawal of approval of ANDAs 89–511, 89–512, and 89–513. FDA withdrew approval of these ANDAs on June 11, 1998.

On July 23, 2001, Aspire Pharmaceuticals, Inc., submitted a citizen petition (Docket No. 01P–0315/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether Roxane's acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Roxane's acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were not withdrawn from sale for reasons of safety or effectiveness. Two grounds support the agency's finding. First, there are drug products with a combination of acetaminophen and codeine phosphate being marketed today with greater than 500 mg of acetaminophen. Second, when FDA's Center for Drug Evaluation and Research Suitability Petition Committee first considered Roxane's suitability petition for its acetaminophen and codeine phosphate drug products, it concluded that the drug products did not need any safety or efficacy studies to support their approval because the proposed change in strength of the acetaminophen component fell within acceptable limits established by the Monograph for Over-the-Counter Internal Analgesic, Antipyretic, and Antirheumatic Drug Products.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously in this document, Roxane's acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been withdrawn from marketing for reasons other than safety or effectiveness. ANDAs that refer to acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, may be approved by the agency .

Dated: April 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–11206 Filed 5–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Comparability Studies for Human Plasma-Derived Therapeutics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Plasma Protein Therapeutics Association (PPTA), entitled ''Comparability Studies for Human Plasma-Derived Therapeutics.'' The workshop will discuss current guidance, critical issues, and approaches for establishing the comparability of human plasma derivatives in order to support changes in manufacturing processes, equipment, or facilities.

Date and Time: The public workshop will be held on May 30, 2002, from 8 a.m. to 5:30 p.m., and on May 31, 2002, from 9 a.m. to 12 noon.

Location: The workshop will be held at the Doubletree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact: HelmsBriscoe Resource One, 12530 Browns Ferry Rd., Herndon, VA

20170, 703–421–5826, FAX 703–444–1737.

Registration: Preregistration is recommended on or before May 29, 2002. Onsite registration will be done on a space-available basis on both days of the workshop, beginning at 7:30 a.m. You may obtain registration forms and information about registration fees from HelmsBriscoe Resource One (see the *Contact* section of this document) or from Joseph Wilczek, Project Manager, at wilczek@cber.fda.gov. Mail or fax your registration information and registration fee to HelmsBriscoe Resource One by May 29, 2002.

If you need special accommodations due to a disability, please contact HelmsBriscoe Resource One at least 7 days in advance.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The public workshop transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

SUPPLEMENTARY INFORMATION: FDA and PPTA are jointly cosponsoring a public workshop on comparability studies for human plasma-derived therapeutics. The workshop will discuss critical issues and approaches for establishing the comparability of human plasma derivatives for supporting changes in manufacturing processes, equipment, or facilities. On May 30, 2002, the workshop will address the three levels of comparability studies—physical/chemical characterization, preclinical studies, and clinical evaluations as they are related to manufacturing changes for a human plasma derivative, as well as information on reporting manufacturing changes, comparability protocols, and several case studies.

On May 31, 2002, the workshop will focus on issues related to comparing fractionation intermediates, a topic specific to the plasma derivative industry. FDA will present historical perspectives and current guidance on cooperative manufacturing arrangements. Industry will discuss the current status of the necessity for fractionation intermediates from sources outside of the company and the criteria for acceptance. The complexities involved in characterizing the source material, intermediates, and the drug products will be discussed. The public workshop agenda will be posted on the Internet at http://www.fda.gov/cber/whatsnew.htm.

Dated: April 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–11208 Filed 5–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Gastrointestinal Drugs Advisory Committee

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 Committees: Nonprescription Drugs Advisory Committee and the Gastrointestinal 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 June 21, 2002, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 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 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will consider the safety and efficacy of new drug application (NDA) 21–229, proposing over-the-counter (OTC) use of PRILOSEC1 (omeprazole magnesium), AstraZeneca LP/Procter and Gamble, for the prevention of the symptoms of frequent heartburn. The sponsor proposes a 20 milligram dose to be taken for 14 days. The background material for this meeting will be posted one working day before the meeting under the Nonprescription Drugs Advisory Committee (NDAC) on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2002 and scroll down to NDAC.)

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 June 12, 2002. Oral presentations from the public will be scheduled on June 21, 2002, between approximately 8:15 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 12, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sandra Titus at least 7 days in advance of the meeting.

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

Dated: April 29, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–11205 Filed 5–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2002 Competitive Application Cycle for the Radiation Exposure Screening and Education Program 93.257

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction.

SUMMARY: In notice document FR Doc. 02–10634, in the issue of Tuesday, April 30, 2002, make the following correction:

On page 21257 in the third column, under section ''Funding Preferences,'' replace the first bullet (which reads