Dated: October 23, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–28599 Filed 10–28–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biologics License Application for Blood Products, and Reporting Changes to an Approved Application; Public Workshop

AGENCY: Food and Drug Administration.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Workshop on the Biologics License Application (BLA) for Blood Products, and Reporting Changes to an Approved Application.'' The topics to be discussed include completing Form FDA 356h; chemistry, manufacturing, and controls information; establishment information; changes requiring supplement submission and approval; changes requiring supplement submission at least 30 days prior to distribution; changes to be described in an annual report; and comparability protocols.

Date and Time: The workshop will be held on December 2, 1997, 8:30 a.m. to 5 p.m.

Location: The workshop will be held at Jack Masur Auditorium, National Institutes of Health, 8800 Rockville Pike, Bldg. 10, Bethesda, MD 20892.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, FAX 301–827–2843.

SUPPLEMENTARY INFORMATION: The public workshop is intended for firms which manufacture or intend to manufacture licensed human blood products, including products for transfusion and source materials for further manufacture. The workshop is also intended for firms planning to supplement their current license for additional products or modifications to current products.

The goals for the workshop are to provide guidance on the application procedures, forms, and documentation needed for the single BLA and guidance on how changes to approved applications are to be reported to the FDA.

Registration: Early registration is recommended on or before Friday, November 21, 1997. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Michelle Priester Healy, Conference Management Associates, Inc., 1010 Wayne Ave., suite 450, Silver Spring, MD 20910, 301–585–8203, FAX 301–585–1186, e-mail confmgmtmd@aol.com. Registration at the site will be done on a space available basis on the day of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to a disability, please contact Michelle Priester Healy at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: October 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–28671 Filed 10–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97P–0220]

Determination That Pseudoephedrine Hydrochloride 120-Milligram Extended-Release Capsules Over-the-Counter Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that pseudoephedrine hydrochloride (Sudafed 12-Hour Capsules) 120-milligram (mg) extended-release capsules over-the-counter (OTC) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for pseudoephedrine hydrochloride 120-mg extended-release capsules.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, 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 (Pub. L. 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 a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's 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 included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(6)), 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 (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to 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 (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated June 3, 1997, and an amendment dated June 24, 1997 (Docket Nos. 97P–0220/CP1 and 97P–0220/AMD1), submitted under 21 CFR 10.30 and 314.161(a)(3), Eurand America, Inc., requested that the agency determine whether pseudoephedrine hydrochloride 120-mg extended-release capsules (OTC) were withdrawn from sale for reasons of safety or effectiveness. Pseudoephedrine hydrochloride 120-mg extended-release capsules, OTC (Sudafed 12-Hour Capsules) were the subject of approved NDA 17–941 held by Burroughs Wellcome Co. Burroughs Wellcome