FOR FURTHER INFORMATION CONTACT: Nicole Mueller, 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 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 (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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, is the subject of approved NDA 08–857 held by Wyeth Pharmaceuticals, a division of Wyeth. PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, is indicated for certain types of allergic reactions and sedation. In a citizen petition dated March 25, 2002 (Docket No. 02P–0127), submitted under § 314.161 and 21 CFR 10.30, PharmaForce, Inc., requested that the agency determine whether PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was withdrawn from sale for reasons of safety or effectiveness. The petitioner seeks this determination in preparation for filing an ANDA for promethazine HCl injection USP 25 mg/mL, 10 mL.

The agency has determined that Wyeth's PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that Wyeth continues to market PHENERGAN for injection in 25 mg/mL and 50 mg/mL, 1-mL vials. The 25 mg/mL, 10 mL product is a multidose vial consisting of the same drug as the 25 mg/mL and 50 mg/mL, 1-mL vials. Also, promethazine HCl is a widely used product that has been marketed for many decades in many dosage forms. Although one potential concern with any multidose injectable product is the possibility of accidental overdose, there is no evidence that the withdrawal from the market of PHENERGAN (promethazine HCl injection) 25 mg/mL, 10 mL, was in any way connected to accidental overdose. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, Wyeth's PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, 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 discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, may be approved by the agency.

Dated: December 8, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–31910 Filed 12–18–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0289]

Medical Devices; Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' This guidance will serve as a special control for the absorbable polydioxanone surgical (PDS) suture which is being reclassified from class III to class II (special controls) elsewhere in this issue of the **Federal Register**. This guidance document is immediately in effect as the special control for the absorbable PDS suture, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

Also, elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend eight other surgical suture device classification regulations in order to designate this guidance as the special control for each such device. After public comments are reviewed, FDA intends to issue a final rule for the eight other surgical sutures and make this guidance effective as the special control guidance for those sutures in addition to the PDS suture, for a total of nine suture types. This guidance is not final nor is it in effect at this time for the eight surgical sutures for which it is being proposed as a special control.

DATES: Submit written or electronic comments concerning this guidance by March 19, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Anthony D. Watson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document describes a means by which surgical suture devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that a manufacturer attempting to establish that its device is substantially equivalent to a predicate class II surgical suture should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA,'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1387) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E were approved under OMB control number 0910–0120.

V. Comments

You may submit to Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance by March 19, 2003. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 16, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–31992 Filed 12–18–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is canceling the meeting of the Pulmonary-Allergy Drugs Advisory Committee scheduled for December 20, 2002. This meeting was announced in the **Federal Register** of November 13, 2002 (67 FR 68878).

FOR FURTHER INFORMATION CONTACT: Kimberly L. Topper, 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, FAX 301–827–6776, or e-mail: topperk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12545.

Dated: December 16, 2002.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 02–32157 Filed 12–17–02; 3:05 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995: