DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. 95D-0002]

Memorandum on the Use of an FDA Cleared or Approved Sterile Connecting Device in Blood Bank Practice; Availability

AGENCY: Food and Drug Administration,

HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a memorandum dated August 5, 1994, to all registered blood establishments. In the August 5, 1994, memorandum, the Center for Biologics Evaluation and Research (CBER) recommends practices and procedures in the use of sterile connecting devices (STCD's). CBER also advises that certain uses of these devices may create a new product or significantly modify a regulated product, such that approval of a license application or an application supplement is required. This memorandum provides information to registered blood establishments on the use of STCD's.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the memorandum to the Congressional and Consumer Affairs Branch (HFM-12), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to INTERNET may request this document from "Mem8-05—94@A1.cber.fda.gov". The document may also be obtained by calling CBER FAX Information System at 301-594-1939 from a FAX machine with a touch tone phone attached or built in. Submit written comments on the memorandum to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The memorandum and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Betty J. Poindexter, Center for Biologics Evaluation and Research (HFM–335),

Evaluation and Research (HFM–335), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. 301–496–2577.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a memorandum to all registered blood establishments on the use of an FDA cleared or approved STCD. STCD's produce sterile welds between two pieces of compatible tubing. This procedure permits sterile connection of a variety of containers and/or needles. This document describes recommended practices and procedures for the use of these devices.

The memorandum provides guidance on the common uses of STCD's as follows: (1) Adding a new or smaller needle to a blood collection set; (2) preparing components; (3) pooling blood products; (4) preparing an aliquot for pediatric use and divided units; (5) connecting additional saline or anticoagulant lines during an automated plasmapheresis procedure; (6) attaching processing solutions; (7) adding an FDA-cleared leukocyte reduction filter; and (8) removing samples from blood product containers for testing.

The memorandum also presents general guidance as well as specific information and examples concerning specifications for submission of applications and application supplements to FDA addressing the use of a STCD. It also includes an appendix with the currently approved dating periods for blood components and source plasma (21 CFR 610.53) and currently recommended dating periods for automated plateletpheresis products (see Revised Guideline for Collection of Platelets, Pheresis (54 FR 3852, January 26, 1989)).

As with other memoranda, FDA does not intend this document to be allinclusive and cautions that not all information may be applicable to all situations. The memorandum is intended to provide information and does not set forth new requirements. The procedures cited in the memorandum are recommendations. FDA anticipates that blood establishments may develop alternative procedures and discuss them with FDA. FDA may find those alternative procedures acceptable. FDA recognizes that advances may continue in the use of STCD's and that this document may become outdated as those advances occur. The memorandum does not bind FDA and does not create or confer any

rights, privileges, or benefits on or for any private person, but is intended merely for guidance.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the memorandum. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether further revisions to the memorandum are warranted.

Dated: February 17, 1995.

William B. Schultz.

Deputy Commissioner for Policy.
[FR Doc. 95–5061 Filed 2–28–95; 8:45 am]
BILLING CODE 4160–01–F

[Docket No. 95N-0051]

Solvay Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 11 Abbreviated Antibiotic Applications and 11 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration,

HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 11 abbreviated antibiotic applications (AADA's) and 11 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: March 31, 1995.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.