batches are not practicable. The sponsor may create an alternative plan to that recommended in order to compare the bioavailability and stability characteristics of the test and production batch. Another major change to the guidelines is the provision of an alternate means by which sponsors may meet the supplemental application recommendations for alternate manufacturing sites and alternate sources of bulk drug substance when multiple NADA's and ANADA's are affected. The sponsor may request that pilot batches of representative drug products within the same dosage form class be manufactured instead of producing pilot batches of all affected drug products.

These ''Animal Drug Manufacturing Guidelines, 1994'' are not intended to be individual stand-alone documents. Much of the information presented in one guideline may be equally important to the correct interpretation of the other guidelines. Therefore, all four guidelines are being issued concurrently.

Guidelines state procedures or practices that may be useful to the persons to whom they are directed, but are not legal requirements. The agency is in the process of revising §§ 10.85(d) and 10.90(b) (21 CFR 10.85(d) and 10.90(b)). Therefore, these guidelines are not being issued under authority of present §§ 10.85(d) and 10.90(b). A person may follow the guideline or may choose to follow alternate procedures or practices. If a person chooses to use alternate procedures or practices, that person may wish to discuss the matter further with the agency to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable to FDA. A guideline does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. When a guideline states a requirement imposed by statute or regulation, however, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guideline.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guideline. 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. The guideline and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered to determine if further revision of the guideline is necessary.

Dated: March 6, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–6006 Filed 3–9–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0058]

Drug Export; Bulk Drug Substance Paclitaxel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that NaPro BioTherapeutics, Inc., has filed an application requesting approval for the export of the bulk human drug substance Paclitaxel for formulation, filling, and packaging into Anzatax™ Injection Concentrate 30 milligrams (mg) paclitaxel in 5 milliliter (mL) vials to Australia.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2073.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that NaPro BioTherapeutics, Inc., 4725 Walnut St., suite 100, Boulder, CO 80301, has filed an application requesting approval for the export of the bulk human drug substance Paclitaxel for formulation, filling, and packaging into Anzatax™ Injection Concentrate 30 mg paclitaxel in 5 mL vials to Australia. This product is indicated for the treatment of refractory ovarian cancer. The application was received and filed in the Center for Drug Evaluation and Research on October 21, 1994, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by March 20, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: March 2, 1995.

Edward Miracco,

Acting Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–6005 Filed 3–9–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

Agency Forms Submitted to the Office of Management and Budget for Clearance

Normally on Fridays, the Social Security Administration publishes a list of information collection packages that have been submitted to the Office of Management and Budget (OMB) for clearance in compliance with P.L. 96–511, The Paperwork Reduction Act. The following clearance packages have been submitted to OMB since the last list was published in the **Federal Register** on February 10, 1995. (Call Reports