the Commission a report, in writing, setting forth in detail in the manner and form in which they have complied with this Order.

IX

It is further ordered that nothing in this Order shall prohibit the companies from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondent Johnson & Johnson Consumer Products, Inc. Its parent corporation, Johnson and Johnson, although not a respondent, also agreed to be bound by the terms of the consent order. Both parent and subsidiary are New Jersey corporations.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

Johnson & Johnson Consumer Products, Inc., manufacturers and sells baby care products, personal care products for adults, and bandages. This matter concerns this company's ''Condom Insurance'' advertisements for its ''K–Y Plus Brand Spermicidal Lubricant with NonOxynol-9'' (''K–Y Plus''). In these advertisements, Johnson & Johnson CPI promote the use of K–Y Plus with condoms as ''insurance'' to protect against unwanted pregnancies, and HIV and other sexually transmitted diseases (''STDs'') in case of condom failure. The ads warn consumers to use K–Y Plus because one in six condoms allegedly fails.

The Commission's complaint charges that respondent's advertising contained false and/or unsubstantiated representations regarding the failure rate of condoms and the effectiveness of K–Y Plus. Specifically, the complaint alleges that the respondent falsely represented that scientific tests or studies show that up to eighteen and one half percent of condoms will fail, leaving users vulnerable to pregnancy and sexually transmitted diseases. The complaint also alleges that the respondent made unsubstantiated claims that: (1) One out of six condoms develops tiny holes during use which are big enough for sperm, HIV and other viruses to pass through; (2) one out of six condoms fails due to mistake in using condoms or through the development of tiny holes during use; (3) K–Y Plus provides protection against the development of tiny holes in condoms during use; and (4) K–Y Plus provides protection against HIV and other viruses.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondent or its parent corporation from engaging in similar acts and practices in the future. Part I of the proposed order would prohibit the companies from making any of the unsubstantiated claims delineated above, or any other claims of a health-related benefit, for K–Y Plus or any other spermicide and/or lubricant, unless at the time of making them, they possess and rely upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence.

Part II of the proposed order includes fencing-in relief, prohibiting the companies from representing, in any manner, directly or by implication, the efficacy of any over-the-counter product as a contraceptive or as a method of protection against the transmission of any sexually-transmitted disease, unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation.

Part III of the proposed order prohibits the companies from misrepresenting in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study relating to any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases.

The proposed order also requires the companies to maintain materials relied upon to substantiate claims covered by the order; to provide a copy of the consent agreement to all employees or representatives involved in the preparation and placement of the company's advertisements, as well as to all company executives and marketing and sales managers; to notify the Commission of any changes in corporate structure that might affect compliance with the order; and to file one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

Concurring Statement of Commissioner Mary L. Azcuenaga in Johnson & Johnson Consumer Protects Inc. File No. 943 3277

In concur in the acceptance of the proposed consent agreement for public comment except to the extent that the proposed order imposes obligations on Johnson & Johnson (the parent company of the respondent Johnson & Johnson Consumer Products Inc.), which is not named in the accompanying complaint.

[FR Doc. 95–26679 Filed 10–26–95; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0344]

Drug Export; AVONEX™, Recombinant Interferon Beta-1a

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Biogen, Inc., has filed an application requesting approval for the export of the human biological product AVONEX™, Recombinant Interferon Beta-1a to the United Kingdom.

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 biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Cathy E. Conn, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2006.

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 human biological products 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 Biogen, Inc., Fourteen Cambridge Center, Cambridge, MA 02142, has filed an application requesting approval for the export of the human biological product AVONEX™, Recombinant Interferon Beta-1a to the United Kingdom. AVONEX™, Recombinant Interferon Beta-1a is indicated for the treatment of relapsing forms of multiple sclerosis. The application was received and filed in the Center for Biologics Evaluation and Research on October 2, 1995, 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 November 6, 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 Biologics Evaluation and Research (21 CFR 5.44).

Dated: October 13, 1995.

James C. Simmons,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 95–26632 Filed 10–26–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0046]

Westmar Oceanside, Inc.; Revocation of U.S. License No. 828

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 828) and the product license issued to Westmar Oceanside, Inc., for the manufacture of Source Plasma. A notice of opportunity for a hearing on a proposal to revoke the licenses was published in the Federal Register of May 6, 1993. In a letter to FDA dated June 1, 1993, a representative of Westmar Oceanside, Inc., indicated that the firm was no longer in business and requested voluntary revocation of the establishment license and product license and thereby waived an opportunity for a hearing.

DATES: The revocation of the establishment license (U.S. License No. 1082) and product license became effective August 3, 1993.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA has revoked the establishment license (U.S. License No. 828) and the product license issued to Westmar Oceanside, Inc., 1024 South Hill St., Oceanside, CA 92504, for the manufacture of Source Plasma.

By letter dated December 11, 1991, FDA advised Westmar Oceanside, Inc., that FDA intended to initiate proceedings to revoke the establishment and product licenses. In the Federal Register of May 6, 1993 (58 FR 26982), FDA published a notice of opportunity for a hearing on the proposed revocation of the licenses pursuant to 21 CFR 12.21(b), as provided in 21 CFR 601.5(b). As described in the notice of opportunity for a hearing, the grounds for the proposed license revocation included the following: (1) The results of the FDA inspection of Westmar Oceanside, Inc., conducted in August through September 1991; (2) the results of an FDA investigation of Westmar Oceanside, Inc., conducted concurrently with the August/September 1991 inspection; (3) a determination by FDA that the deviations documented during the August/September 1991 inspection and investigation showed serious noncompliance with the applicable biologics regulations and standards of the firm's license; and (4) a determination by FDA that the violations at the firm were significant and willful. Documentation in support of the proposed revocation had been placed on file for public examination with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

The notice of opportunity for a hearing provided 30 days for Westmar Oceanside, Inc., to submit a written request for a hearing, as specified in 21 CFR 12.21(b), and 60 days to submit any data or information justifying a hearing. The notice of opportunity for a hearing provided 60 days for other interested persons to submit written comments on the proposed revocation action. A representative for Westmar Oceanside, Inc., responded to the notice of opportunity for a hearing by letter dated June 1, 1993. The letter stated that the firm was no longer in business and requested voluntary revocation of the firm's establishment license and product license and thereby waived an opportunity for a hearing. In a letter dated August 3, 1993, to the firm, FDA revoked the establishment license (U.S. License No. 828) and the product license issued to Westmar Oceanside, Inc.

No other written comments on the proposed revocation were received within the prescribed 60 days specified in the notice of opportunity for a hearing.

FDA has placed a copy of FDA's August 3, 1993, letter on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. This document is available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under 21 CFR 601.5, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 828) and the product license issued to Westmar Oceanside, Inc., for the manufacture of Source Plasma were revoked, effective August 3, 1993.

This notice issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67.