participants. After the first year the participants plan to evaluate the arrangement, thereafter, no less than once every five years. It may be amended by mutual written consent or terminated by either participant upon a 60 day written notice to the other participant.

This Arrangement is not intended to create any legal obligations under international law. In Witness Whereof the undersigned, being duly authorized by their respective Government agencies, have signed this Cooperative Arrangement.

FOR THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA
William B. Schultz,
Title: Deputy Commissioner for Policy.
Date: December 20, 1995
Place: Rockville, Maryland

FOR THE MINISTRY OF AGRICULTURE
NEW ZEALAND
L. J. Wood
Title: Ambassador of New Zealand
Date: December 20, 1995
Place: Rockville, Maryland

FOR THE MINISTRY OF HEALTH
NEW ZEALAND
L. J. Wood
Title: Ambassador of New Zealand
Date: December 20, 1995
Place: Rockville, Maryland

Annex A

I. Performance Verification

The United States FDA, and the New Zealand's MAF and MH, understand that the participants of the importing country can audit the exporting country's seafood control system to verify that the terms of the arrangement are being met. These system checks may take place upon request of the participants of the importing country. The costs of system check visits are the responsibility of the visiting participant.

Verification may take the form of:

- ongoing exchange of information toward continuing transparency;
- reviewing the competent authorities' compliance/audit programs;
- verifying the efficacy of the total program in meeting the requirements of the importing country;
- checks of products on importation at an appropriate frequency;
- program checks.

II. Information Exchange/Transparency

A. Participants intend to cooperate and exchange information in scientific areas.
B. The participants intend to put in place a system for the uniform and systematic exchange of information, so as to provide assurance and engender confidence in each other and to demonstrate the efficacy of the programs controlled.
C. In particular the liaison officials intend to provide each other copies of:

1. Proposed changes in requirements developed by each side where they affect the other party before they become effective.
2. Changes in requirements including:
   a. legislation
   b. rules
   c. enforcement policy documents
   d. guidelines
   e. methods and procedures for sampling and analysis
   f. inspection procedures
   g. notice of surveillance programs or assignments requiring sampling at importation of a fish or fishery product (i.e., for data base development)
3. Documentation regarding any fish or fishery products from the other country found to be in non-compliance with requirements upon importation including information on:
   a. product name
   b. manufacturer/shipper name
   c. processor name
   d. reason for detention
   e. product lot and certificate number (if applicable)
   f. sampling procedures
   g. methods of analysis and confirmation
   h. port of entry
4. Documents regarding any fish or fishery product found to be in non-compliance by the exporting country after exportation to the other (e.g., recalls):
   a. product
   b. manufacturer/shipper name
   c. processor name
   d. reason for recall
   e. product lot and certificate number (if applicable)
   f. consignee(s)
   g. dates
   h. amount shipped

[FR Doc. 96–4187 Filed 2–23–96; 8:45 am]
BILLING CODE 4160–01–F

[Docket No. 94P–0206]

Determination that Evans Blue Dye Injection Was 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 Evans Blue Dye Injection, an approved new drug application (NDA) held by Parke-Davis & Co., a division of Warner-Lambert Co., was not withdrawn from sale for reasons of safety or effectiveness and is relisting the drug in its publication entitled ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' This will allow sponsors to submit abbreviated new drug applications (ANDA's) for Evans Blue Dye Injection.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law 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 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 an 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.

On June 6, 1994, the New World Trading Corp. submitted a citizen petition (Docket No. 94P–0206/CP1) under 21 CFR 10.25(a) and 10.30 requesting that the agency determine whether Evans Blue Dye Injection was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to relist the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Evans Blue Dye Injection was the subject of approved NDA 8–041 held by Parke-Davis & Co., a division of Warner Lambert Co. Evans Blue Dye Injection was withdrawn from sale in June 1978, and the NDA was withdrawn, with the consent of the sponsor, in a notice

published in the Federal Register of November 15, 1990 (55 FR 47807).

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that Evans Blue Dye Injection was not withdrawn from sale for reasons of safety or effectiveness and will relist Evans Blue Dye Injection in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have had their approvals withdrawn for reasons other than safety and efficacy subsequent to being discontinued from marketing. ANDA's that refer to Evans Blue Dye Injection may be submitted to the agency.

Dated: February 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4287 Filed 2–23–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. March 4, 1996, 8:30 a.m., Gaithersburg Hilton, Salons D and E, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Hilton. Attendees requiring overnight accommodations may contact the hotel at 301–977–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4:30 p.m.; Ramiah Subramanian, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Circulatory Systems Devices Panel of the Medical Devices Advisory Committee, code 12625.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 26, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss general issues related to two premarket approval applications: (1) A stent for a peripheral vascular use, and (2) an angioplasty balloon.

FDA regrets that it was unable to publish this notice 15 days prior to the March 4, 1996, Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency feels that the issue needs to be brought to public discussion urgently, and qualified members of the Circulatory System Devices Panel of the Medical Devices Advisory Committee were available at this time, the agency decided that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. March 7, l996, 3 p.m., Food and Drug Administration, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open committee discussion, 3 p.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; Nancy T. Cherry or Sandy Salins, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person.

Open committee discussion. The committee will discuss the influenza virus vaccine formulation for 1996 and 1997.

FDA regrets that it was unable to publish this notice 15 days prior to the March 7, 1996, Vaccines and Related Biological Products Advisory Committee meeting. Because the agency feels that the issue needs to be brought to public discussion urgently, and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the agency decided that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.