encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before March 27, 1996, submit to the Dockets Management Branch (address above) written comments. 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 office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: February 8, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–4188 Filed 2–23–96; 8:45 am]

BILLING CODE 4160–01–P

Cooperative Arrangement Between the Food and Drug Administration and New Zealand Covering Seafood

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a Cooperative Arrangement between FDA and the Ministry of Health and the Ministry of Agriculture of New Zealand. The purpose of the Cooperative Arrangement is the recognition of each as competent authorities, having systems to ensure safe, wholesome, and truthfully labeled fish and fishery products.

DATES: The agreement became effective December 20, 1995.

FOR FURTHER INFORMATION CONTACT: Janet J. Walraven, Office of Seafood (HFS–416), Food and Drug Administration, 200 C. St., SW., Washington DC 20204, 202–418–3160.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the Federal Register, the agency is publishing notice of this cooperative arrangement. Because this arrangement only encourages each party to achieve compliance with the other's regulatory requirements, it does not contain a determination of equivalency subject to the Uruguay Round Agreements Act (see 19 U.S.C. 2578a).

Dated: February 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

225–96–2004

Cooperative Arrangement Between Department of Health and Human Services, The Food and Drug Administration, United States of America and The Ministry of Agriculture and The Ministry of Health, New Zealand, to Ensure The Safety of Imported Fish and Fishery Products

The Department of Health and Human Services, Food and Drug Administration of the United States of America
on the one part, and
The Ministry of Agriculture, and The Ministry of Health of New Zealand
on the other part,
Desiring to safeguard public health and to ensure wholesomeness and properly labeled fish and fishery products;
Recognizing that the United States, represented by the Department of Health and Human Services, Food and Drug Administration (FDA), and New Zealand represented by the Ministry of Agriculture (MAF) and the Ministry of Health (MH), as competent authorities, each have systems to ensure safe, wholesome and properly labeled fish and fishery products;
Noting that these control measures arise from authorities that are the United States Federal Food, Drug, and Cosmetic Act (FFD&C Act), Public Health Service Act (PHS Act), and Fair Packaging and Labeling Act; and the New Zealand Meat Act 1981 and Food Act 1981;
Noting that these control measures are implemented by regulations under the aforementioned authorities that are the New Zealand Fish Export Processing Regulations 1995 and Title 21 of the United States Code of Federal Regulations;
Reaffirming that training programs and audits are in place in both countries that provide trained and qualified inspection forces which are the New Zealand Circuit Inspector Training program, supported by an inspector audit program, and FDA investigator and laboratory analyst education and training requirements with ongoing performance evaluation;
Noting that the organizations, FDA and MAF and MH, have resources to carry out the compliance programs, policies and laboratory support activities that are funded in New Zealand by government appropriation and fee-for-service arrangements and funded in the United States by government appropriation at the Federal and State level;
Noting that the United States FDA has carried out extensive comparative reviews of the New Zealand control system and has verified the performance of that system, and New Zealand has issued a finding of acceptability of the United States FDA control system;
Noting that New Zealand fish and fishery products have met U.S. FDA standards in the past based on FDA import inspections;
Noting that this arrangement offers benefits for both consumer protection and trade in that it is an effective and efficient tool for enhancing the safety of imports while reducing the resources that need to be expended to monitor imports from the countries involved.
Have reached an understanding that the NZ export controls enhance the likelihood of compliance by NZ seafood with FDA's safety, quality, and labeling requirements; that the FDA processor controls for seafood enhance the likelihood of compliance by US seafood with NZ MH safety, quality, and labeling requirements; and that the FDA, MAF and MH plan to take this understanding into account in determining frequency of border checks when fish and fishery products are offered for entry into their respective countries.

I. Substance of Arrangement

A. Definitions

1. *Fish* means fresh or saltwater finfish, crustaceans, mollusks, and other forms of aquatic animal life (including, but not limited to, jellyfish, sea cucumber, sea urchin, frog, alligator, aquatic turtle), but excluding birds and mammals, where such animals are intended for human consumption.
2. *Fishery* products means any edible human food product consisting in whole of fish or a product containing a portion of fish, including fish that has been processed in any manner, in which the characterizing ingredient is fish.
3. *Fresh* means or implies that the food is unprocessed, that the food is in its raw state, and that it has not been frozen or subjected to any form of thermal processing or any other form of preservation.
4. *Fresh frozen* means that the food was quickly frozen while still fresh.
5. *Participants* means the United States Food and Drug Administration (FDA) and New Zealand's Ministry of Agriculture (MAF) and New Zealand Ministry of Health (MH).
6. *Transparency* refers to the ability to have access to relevant information about regulatory and technical measures so that their meanings, applications, and requirements are clear. It can be accomplished through the mutual exchange of information and assistance between trading partners, whereby each provides the other with the texts of legal, regulatory (except in-process legal and

regulatory actions), and technical measures, guidance documents, and other information that apply to the commodities subject to the arrangement.
7. *Wholesomeness* means the food is not filthy, putrid, decomposed, or otherwise unfit for food.

B. Scope

This arrangement covers:
1. Fish and fishery products intended for human consumption except fresh and fresh frozen (molluscan) shellfish.
2. Food safety, wholesomeness, and labeling requirements for the fish and fishery products covered.

C. General Principles

1. The participants understand that each one of their country's systems to ensure safe, wholesome and properly labeled fish and fishery products enhances the likelihood that exported fish and fishery products will comply with the other country's safety, quality and labeling requirements. The participants intend to take this understanding into account in determining the frequency of border checks when fish and fishery products are offered for entry into their respective countries.
2. The participants intend to exchange information to ensure transparency as described in Annex A.
3. The participants intend to establish procedures for cooperation as described below.
   a. The participants plan to meet regularly, at least every two years, to ensure that the basis for the arrangement continues to exist.
   b. In cases of serious and immediate concern with respect to public health or safety, the participants intend to notify the designated Liaison Officers immediately, and written confirmation of the concerns to the Liaison Officers should follow within 48 hours.
   c. Where a Participant has concerns regarding a potential risk to public health, consultations regarding the situation should, upon request of that Participant, take place as soon as possible, and in any case within 14 days, of such a request. Each Participant will endeavor in such situations to provide all the information necessary to reach a mutually acceptable solution.
4. Nothing in this arrangement will in any way abrogate the responsibility or authority of the U.S. Food and Drug Administration under section 801 of the Federal Food, Drug and Cosmetic Act to examine any food product being offered for entry into the United States or under any other law administered by FDA. Neither will it abrogate the responsibility or authority of the New Zealand Government Minister of Agriculture pursuant to The Meat Act 1981 or the Minister of Health pursuant to the Food Act 1981.
5. Nothing in this arrangement precludes either the U.S. FDA, MAF or MH of New Zealand from exercising responsibility to ensure the safety, wholesomeness, or properly labeled seafood and seafood products being allowed to enter that country's commercial marketing channels.
6. All activities undertaken pursuant to this arrangement are to be conducted in accordance with the laws and regulations of the United States and of New Zealand and are subject to the availability of personnel, resources and appropriated funds.

D. Specific Responsibilities

1. MAF intends to provide FDA with:
   a. a list of premises licensed by MAF to process fish and fishery products for export. MAF intends to update this list as needed for the FDA Liaison, Office of Seafood.
   b. a government health certificate for each consignment of fish and fishery products exported to the United States.
   c. an annual summary showing results of compliance audits conducted by the MAF Compliance Group for fish and fishery products, to the attention of the FDA Liaison, Office of Seafood.
   d. in the event that the U.S. establishes a mandatory U.S. seafood Hazard Analysis Critical Control Points (HACCP) program, N.Z. MAF intends to demonstrate to the FDA Liaison, Office of Seafood, how their system implements and ensures that fish and fishery products are produced under a HACCP-based program in compliance or equivalent with the U.S. seafood HACCP program.
2. FDA intends to provide MAF with:
   a. a list of U.S. seafood processing firms found to require official U.S. Government regulatory action and further details upon request. FDA intends to update this list as needed.
   b. an annual report of FDA Field Seafood Accomplishments.
   c. in the event that the U.S. establishes a mandatory U.S. seafood HACCP program, a copy of the requirements of that program.

E. Audits

It is understood that each participant will strive to facilitate the other participant's reasonable access to any sites in the exporting country that are involved in the export of fish and fishery products for the purpose of auditing the exporting country's seafood regulatory system, of verifying that applicable elements of the arrangement are being met, and of carrying out checks on the continued compliance with the arrangement and system by producers and exporters of fish and fishery products to the importing country. The cost of on-site visits will be the responsibility of the visiting participant.

Some factors to be considered in auditing both countries' seafood regulatory systems are presented in Annex A.

F. Cooperation procedures

The Participants undertake to resolve differences by:
1. Use of professional judgment as well as objective criteria, with attempts made to resolve differences by technical discussions at the appropriate level; and
2. Where issues remain unsolved after technical discussions as stipulated above, the participants intend to schedule discussions between the Director, Office of Seafood of the U.S. FDA and either the Chief Meat Veterinary Officer of the New Zealand Ministry of Agriculture, or the Manager of Food Administration, New Zealand Ministry of Health, or their designees. The nature of the issue will determine the competent New Zealand authority.

G. Application

1. The Participants plan to maintain communications so that the terms of this arrangement are fulfilled.
2. The Participants intend to document communications and decisions. Those matters that need to be referred to a higher level will be identified and referred to that level.
3. Whenever specific issues requiring attention are identified, the participants intend to establish a timetable to resolve those issues.

II. Participants

a. The U.S. Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, U.S.
b. Ministry of Agriculture, ASB Bank House, 101–103 The Terrace, P.O. Box 2526, Wellington, New Zealand; Ministry of Health, Food Administration, P.O Box 5013, 133 Molesworth St., Wellington, New Zealand

III. Liaison Officers

A. New Zealand Ministry of Agriculture:

The Ministry of Health, the body responsible for the safety of domestic and imported food products, defers to the Ministry of Agriculture to act as liaison officers with the U.S. FDA related to matters of U.S. fish and fishery products imported to New Zealand.

Chief Meat Veterinary Officer, Ministry of Agriculture, ASB Bank House, 101–103 The Terrace, P.O. Box 2526, Wellington, New Zealand, Phone: 011–64–4–4744125, FAX: 011–64–4–4744240

Counsellor (Veterinary Services), New Zealand Embassy, 37 Observatory Circle N.W., Washington, DC 20008, United States of America, Phone: (202) 328–4861, FAX: (202) 332–4309

B. United States Food and Drug Administration:

Director, Office of Seafood, Center for Food Safety and Applied Nutrition, 200 C Street, S.W., Washington, DC 20204, United States of America, Phone: (202) 418–3133, FAX: (202) 418–3196

Director, International Activities Staff, Center for Food Safety and Applied Nutrition, 200 C Street, S.W., Washington, DC 20204, United States of America, Phone: (202) 205–5042, FAX: (202) 205–0165

IV. Period of Arrangement

Cooperation under this arrangement will begin on the last date of signature of the

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