communication and institutional infrastructure of the People Living with HIV/AIDS (PLWHA) Networks in the area. The Catalog of Federal Domestic Assistance number for this program is 93.941.

B. Eligible Applicant

Assistance will be provided only to the Caribbean Regional Network of Persons Living with HIV/AIDS (CRN+). No other applications are solicited. This is the original, and only network of PLWHA in this region that links twenty-seven islands, seven active national networks, and a functioning regional office based in Port of Spain, Trinidad. CRN+ also has the support of the Global Network of PLWHA and the International Community of Women Living With HIV/AIDS. Since 1996, CRN+ has addressed the most pertinent issues relating to HIV/AIDS and plays an integrally esteemed role throughout the region among PLWHA and partner agencies alike. CRN+ is a member of the Pan Caribbean Partnership Against AIDS (PANCAP) that developed and implements the Caribbean regional strategic plan to combat HIV and AIDS.

C. Funding

Approximately $60,000 is available in FY 2003 to fund this award. It is expected that the award will begin on or before September 15, 2003, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For technical questions about this program, contact: Ethleen Lloyd, CDC GAP Caribbean Regional Office, 9 Alexandra Street, Port of Spain, Trinidad and Tobago, Phone: 1–868–622–3153, E-mail: *esl1@cdc.gov.*

Dated: August 5, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–20355 Filed 8–8–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0350]

Sankyo Pharma, Inc.; Withdrawal of Approval of a New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for PRELAY (troglitazone) Tablets held by Sankyo Pharma, Inc. (Sankyo Pharma), 399 Thornall St., Edison, NJ 08837. Sankyo Pharma has requested that approval of this application be withdrawn because the product is not being marketed, thereby waiving its opportunity for a hearing.

DATES: Effective August 11, 2003.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In a letter dated December 31, 2002, Sankyo Pharma requested that FDA withdraw approval, under § 314.150(d) (21 CFR 314.150(d)), of NDA 20–719 for PRELAY (troglitazone) Tablets. Sankyo U.S.A. Corp. (Sankyo U.S.A.) filed NDA 20–719 for PRELAY concurrently with Warner-Lambert Co.'s NDA 20–720 for REZULIN. Both these applications were for troglitazone tablets. Sankyo U.S.A. merged into Sankyo Pharma in December 1999. Neither Sankyo U.S.A. nor Sankyo Pharma has ever marketed PRELAY, and Sankyo Pharma has no plans to market troglitazone in the future. FDA has determined that never marketing an approved drug product is equivalent to withdrawing the drug from sale. PRELAY, a treatment for type 2 diabetes, was voluntarily withdrawn after review of safety data showed that REZULIN is more toxic to the liver than two other more recently approved drugs that offer a similar benefit (see the REZULIN withdrawal notice that published in the **Federal Register** of January 10, 2003 (68 FR 1469)). Sankyo Pharma waived its opportunity for a hearing, provided under § 314.150(a) and (b).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105(a)), approval of the NDA 20–719, and all amendments and supplements thereto, is withdrawn, effective August 11, 2003. Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and 331(d)).

Dated: July 10, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–20383 Filed 8–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–03–8001]

Memorandum of Understanding Between the Department of Health and Human Services of the United States Through the Food and Drug Administration and the Ministry of Health of the United Mexican States Through the Federal Commission For Protection From Sanitary Risks Covering the Safety and Quality of Fresh and Frozen Aquacultured Molluscan Shellfish Exported From the United Mexican States to the United States of America

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Department of Health and Human Services of the United States of America, through the Food and Drug Administration (FDA) and the Ministry of Health of the United Mexican States, through the Federal Commission for Protection from Sanitary Risks. This understanding is in keeping with the beneficial and cooperative work conducted under the terms of a 1988 MOU concerning the safety and quality of molluscan shellfish exported to the United States from the United Mexican States. The purpose of the MOU is to establish the set of guidelines to be implemented for assuring that molluscan shellfish exported from the United Mexican States and offered for import into the United States of America are safe for human consumption and are harvested, processed, transported, and labeled in accordance with the provision of the U.S. National Shellfish Sanitation Program, the applicable requirements of

the Federal Food, Drug, and Cosmetic Act, and other related public health laws.

DATES: The agreement became effective June 18, 2003.

FOR FURTHER INFORMATION CONTACT: Paul W. Distefano, Center for Food Safety and Applied Nutrition, (HFS–417), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1410.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c) which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: July 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA THROUGH THE FOOD AND DRUG ADMINISTRATION

AND THE

MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES THROUGH THE FEDERAL COMMISSION FOR PROTECTION FROM SANITARY RISKS

COVERING THE SAFETY AND QUALITY OF FRESH AND FROZEN AQUACULTURED MOLLUSCAN SHELLFISH EXPORTED FROM THE UNITED MEXICAN STATES TO THE UNITED STATES OF AMERICA

The Department of Health and Human Services of the United States of America, through the Food and Drug Administration (FDA) and the Ministry of Health of the United Mexican States, through the Federal Commission for Protection from Sanitary Risks (COFEPRIS), hereinafter referred as "The Participants",

Desiring to safeguard public health and to ensure the safety and quality of fresh and frozen aquacultured molluscan shellfish that are or may be exported into the United States of America, and

In keeping with the beneficial and cooperative work conducted under the terms of a 1988 Memorandum of Understanding concerning the safety and quality of molluscan shellfish exported to the United States of America from the United Mexican States, and

Recognizing that the Participants have held technical consultations leading to the successful development and implementation of an effective molluscan shellfish sanitation program in the United Mexican States for molluscan shellfish, and

Recognizing that nothing in this Memorandum of Understanding (MOU) will in any way abrogate the responsibility or authority of the FDA under section 801 of the Federal Food, Drug, and Cosmetic Act to examine, and, where appropriate, refuse admission of, any food product being offered for entry into the United States of America or to comply with and enforce any other law administered by the FDA, and

Acknowledging that the FDA recognizes the Mexican Shellfish Sanitation Program (MSSP) and finds that the MSSP adequately meets U.S. National Shellfish Sanitation Program (NSSP) guidelines, and that COFEPRIS retains the overall responsibility for the MSSP and coordinates participation of Mexican State Governments in the Molluscan Shellfish Program;

Have hereby reached the following understanding:

ARTICLE I
Purpose

The purpose of this MOU is to establish the set of guidelines to be implemented for assuring that molluscan shellfish exported from the United Mexican States and offered for import into the United States of America are safe for human consumption and are harvested, processed, transported, and labeled in accordance with the provisions of the NSSP Model Ordinance and the applicable requirements of the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, and Title 21 of the U.S. Code of Federal Regulations.

ARTICLE II
Definitions

For the purpose of this MOU the words listed below will have the following meaning:

1. Approved means the classification used to identify a growing area where the harvest of molluscan shellfish for direct marketing is allowed.

2. Aquaculture means the cultivation of seed in natural or artificial growing areas, or the cultivation of shellstock other than seed in natural or artificial growing areas.

3. Central file means the single location where COFEPRIS maintains a copy of all information, data, reports, and maps associated with the MSSP.

4. Lot of shellstock means a collection of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area harvested by one or more harvesters.

5. Lot of shucked molluscan shellfish means a collection of containers of shucked molluscan shellfish of no more than one day's harvest from a single defined growing area, produced under conditions as nearly uniform as possible, and designated by a common container code or marking.

6. Marine biotoxins means any poisonous compound produced by marine microorganisms and accumulated by shellstock.

7. Mexican Shellfish Sanitation Program (MSSP) means the regulatory control program in the United Mexican States designed to ensure the safety of molluscan shellfish intended for export to the United States of America through the implementation of control measures set forth in the NSSP.

8. Molluscan Shellfish, means all edible species of aquacultured oysters, clams, mussels, and whole or roe on scallops; either shucked or in the shell, fresh or frozen, whole or in part.

9. National Shellfish Sanitation Program (NSSP) means the cooperative state (domestic and foreign)-FDA-industry program to ensure the safety and quality of molluscan shellfish intended for human consumption. Guidelines for ensuring the safety and quality of molluscan shellfish are set forth in the NSSP Model Ordinance.

10. Patrol means the active control of molluscan shellfish harvesting to ensure that only molluscan shellfish from approved areas are harvested, processed, and shipped.

11. Relay means the transfer of shellstock from unapproved areas to approved areas for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

12. Sanitary Survey Report means the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a molluscan shellfish growing area.

13. Shellstock means live molluscan shellfish in the shell.

ARTICLE III
Obligations of the Participants

A. RESPONSIBILITIES OF COFEPRIS

1. COFEPRIS assumes the commitment of overall responsibility for the coordination and implementation of the MSSP.

2. COFEPRIS intends to:

   a. Maintain legal, administrative, safety, quality, and sanitary controls over molluscan shellfish intended for export to the United States of America by certified Mexican processors.

   b. Ensure that the MSSP conforms to the NSSP, including, but not limited to:

      i. classifying molluscan shellfish growing waters;

      ii. preparing sanitary survey reports and maintaining sanitary survey reports and all related data in the central file;

      iii. updating sanitary survey reports annually and triennially for the purpose of ensuring the proper classification of each molluscan shellfish growing area;

iv. approving and supervising harvesting and relaying operations and ensuring proper labeling and identification of molluscan shellfish in accordance with the NSSP;

v. restricting the harvest of molluscan shellfish from unapproved growing areas, controlling the harvest of molluscan shellfish from unapproved growing areas, and taking enforcement action against persons or firms harvesting from unapproved growing areas;

vi. prohibiting the harvest of molluscan shellfish from growing areas in response to contamination emergencies and for rescinding such prohibitions when water quality data or marine biotoxin analyses demonstrate that the area meets NSSP approved area criteria;

vii. recalling unsafe molluscan shellfish when the responsible processor fails to carry out the necessary product recall;

viii. maintaining NSSP conforming laboratories certified to participate in the MSSP;

ix. inspecting processors that process fresh or frozen aquacultured molluscan shellfish for export to the United States of America to ensure compliance with NSSP controls;

x. certifying processors exporting fresh or frozen aquacultured molluscan shellfish to the United States of America in accordance with the NSSP for listing on FDA's Interstate Certified Shellfish Shippers List (ICSSL);

xi. notifying FDA of the name, location and certification number of MSSP certified processors exporting to the United States of America on Form FD-3038, "Shellfish Dealer Certification";

xii. canceling the certification of any processor that:

operates out of compliance with the NSSP;

ships molluscan shellfish from unapproved growing areas; or

ships molluscan shellfish that otherwise do not conform to the requirements of the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, or Title 21 of the U.S. Code of Federal Regulations.

fails to recall molluscan shellfish determined to be unsafe for human consumption;

xiii. ensuring that each container in a lot of molluscan shellfish certified for export to the United States of America is properly labeled in accordance with the NSSP;

xiv. maintaining a central file of all MSSP records, including an English version of all sanitary survey reports, patrol reports, and laboratory evaluation reports and make them available to FDA upon request;

xv. providing FDA evaluation reports, interpretations, laboratory quality assurance program information, and other molluscan shellfish program information from FDA to federal and state government agencies having responsibility for the MSSP;

xvi. reviewing, at least annually, the level of conformity with the NSSP and summarizing the findings in a written report and providing an English translation of the report to FDA annually;

xvii. providing FDA with information concerning current or potential public health problems affecting molluscan shellfish intended for export to the United States of America; and

xviii. making travel arrangements in the United Mexican States for, and conducting joint inspections with, FDA evaluation officers at FDA's request. Providing transportation for FDA officials while in the United Mexican States.

c. Permit the harvesting of molluscan shellfish for processing by MSSP certified processors and shipment to the United States of America only from growing areas approved by COFEPRIS with concurrence from the FDA.

d. Within 30 days of written notification from FDA of NSSP deficiencies, develop a written Corrective Action Plan, and submit it to FDA for review and concurrence. If a Plan is not developed within 30 days, FDA will remove Mexican processors from the ICSSL and/or take other appropriate action to stop molluscan shellfish from the United Mexican States from entering the United States of America. Such action should remain in effect until all MSSP deficiencies have been corrected and FDA has determined that the MSSP is in compliance with the NSSP.

3. COFEPRIS may designate a MSSP laboratory evaluation officer to:

a. certify laboratories participating in the MSSP;

b. periodically evaluate certified MSSP laboratories to verify compliance with the NSSP and maintain laboratory quality assurance procedures;

c. maintain a marine biotoxin monitoring program for growing areas where molluscan shellfish are harvested for export to the United States of America;

d. maintain a split-sample program among MSSP laboratories for evaluating uniform microbiological laboratory practices;

e. notify FDA of laboratories not in compliance with the NSSP; and

f. prevent MSSP laboratories not in compliance with the NSSP from participating in the MSSP.

4. COFEPRIS should update the MSSP Model Ordinance to be consistent with published NSSP Model Ordinance revisions. COFEPRIS should provide an English version of all updates to FDA for review and concurrence.

5. Any change in responsibility from COFEPRIS to another authority must be reported to FDA within 30 days of such change. A change from COFEPRIS to a new authority may require re-evaluation of the MSSP by FDA.

6. Mexican states goverments participating in the MSSP are equally responsible for ensuring the safety and quality of molluscan shellfish exported to the United States of America.

B. RESPONSIBILITIES OF THE FDA

FDA intends to:

1. Accept the United Mexican States as a participant in the NSSP and the Interstate Shellfish Sanitation Conference (ISSC), cooperative research programs, seminars, training courses, and other NSSP activities and have COFEPRIS certify Mexican processors for inclusion in FDA's ICSSL.
2. Publish the names, locations, and certification numbers of Mexican firms certified by COFEPRIS in the monthly publication of the ICSSL upon receipt of Form FD-3038.

3. Provide training and technical assistance to COFEPRIS, subject to the availability of funds and personnel for such purposes.

4. Inform COFEPRIS of the reasons for any detention of certified molluscan shellfish shipments from the United Mexican States.

5. Participate with COFEPRIS in joint evaluations of the MSSP. Joint evaluations will be conducted to ascertain the level of conformity with the requirements of the NSSP and

with the responsibilities specified in this MOU. FDA should pay round trip transportation expenses between the United States of America and the United Mexican States and the per diem of the members of the FDA evaluation team while in the United Mexican States.

6. Notify COFEPRIS of NSSP deficiencies and request that COFEPRIS submit, within 30 days, a written Corrective Action Plan to FDA for review and concurrence. If a Plan is not developed within 30 days or if the deficiencies are not corrected in accordance with the Plan, FDA will remove Mexican processors from the ICSSL and/or take other appropriate action to stop Mexican molluscan shellfish from entering the United States of America. In case of a serious public health threat, this 30 day period may be reduced or eliminated. Such action should remain in effect until all NSSP deficiencies have been corrected and FDA has determined that the MSSP is in compliance with the NSSP.

7. Remove individual Mexican processors from the ICSSL when it is determined by FDA or COFEPRIS that a processor is not in compliance with the NSSP or when an imminent health hazard exists with a processor's product.

8. Report any change in responsibility from FDA to another federal authority to COFEPRIS within 30 days of such change.

ARTICLE IV
Technical Information Exchange

The working language for documents exchanged under this MOU should be English. The Participants plan to share expertise, provide assistance, and exchange information. Such mutual cooperation may include, but is not be limited to:

1. Exchanging information concerning proposed and final changes in MSSP operations and procedures including, but not limited to:

a. methods and procedures for sampling;

b. methods of analysis;

c. methods of confirmation;

d. administrative guidelines, tolerances, specification standards, and nomenclature;

e. reference standards; and

f. inspection procedures.

2. Providing written notification to the other Participant within 30 days of changes in liaison officers. Changing liaison officers does not otherwise constitute a change in the provisions of this MOU.

3. Facilitating the exchange of information between COFEPRIS and U.S. Federal and State agencies concerned with the introduction and proliferation of exotic organisms that might be carried by Mexican molluscan shellfish.

ARTICLE V
Liaison Officers

In order to obtain an adequate follow up of the cooperation activities derived from this MOU, the liaison officers will be

A. For COFEPRIS:

Director (a) General de Control Sanitario de Productos y Servicios
Comision Federal para la Proteccion Contra Riegos Sanitarios (COFEPRIS)
Av. Monterrey No. 33
Col. Roma C.P. 06700
Del. Cuauhtemoc
Mexico, D.F., Estados Unidos Mexicanos
Telephone: 011 52 55 5080 5200 ext. 1254; 1259; 1230

B. For the Food and Drug Administration:

Director, Office of Seafood
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
5 100 Paint Branch Parkway (HFS-400)
College Park, MD 20740
The United States of America
Telephone: 01301436-2300

ARTICLE VI
Final Dispositions

Activities under this MOU commence upon signature by both Participants and continue for five (5) years. It may be extended with written consent of both Participants.

The Participants intend to evaluate the MOU during the five-year period. It may be amended by written consent of both Participants, specifying the date in which the activities will commence.

All activities undertaken pursuant to this MOU are to be conducted in accordance with the laws and regulations of the United States of America and the United Mexican States and are subject to the availability of personnel, resources, and appropriated funds.

This MOU is not intended to create any obligations under international or other law.

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective Government agencies, have signed this Memorandum of Understanding.

Signed in San Antonio, Texas on this Eighteenth day of June, in quadruplicate: two copies each in English and Spanish languages, respectively,

FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

MARK B. MC CLELLAN
Commissioner,
Food and Drug Administration

From the Food and Drug Administration

FOR THE MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES

LIC. ERNESTO ENRIQUEZ RUBIO
Federal Commissioner for the Protection from Sanitary Risks

From the Federal Commission for the Protection from Sanitary Risks

MEMORANDUM DE ENTENDIMIENTO

ENTRE

EL DEPARTAMENTO DE SALUD Y SERVICIOS SOCIALES DE LOS ESTADOS UNIDOS DE AMERICA A TRAVES DE LA ADMINISTRACION DE ALIMENTOS Y FARMACOS

Y

LA SECRETARIA DE SALUD DE LOS ESTADOS UNIDOS MEXICANOS A TRAVES DE LA COMISION FEDERAL PARA LA PROTECCION CONTRA RIESGOS SANITARIOS

SOBRE

LA INOCUIDAD Y CALIDAD DE LOS MOLUSCOS BIVALVOS DE ACUICULTURA, FRESCOS Y CONGELADOS, EXPORTADOS DE LOS ESTADOS UNIDOS MEXICANOS A LOS ESTADOS UNIDOS DE AMERICA

El Departamento de Salud y Servicios Sociales *(Department of Health and Human Services)* de los Estados Unidos de America, a traves de la Administración de Alimentos y Farmacos *(Food and Drug Administration,* FDA), y la Secretaria de Salud de los Estados Unidos Mexicanos, a traves de la Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), en to sucesivo denominadas como "las Partes";

DESEOSOS de salvaguardar la salud piublica y de velar por la inocuidad y calidad de los moluscos bivalvos provenientes de la acuicultura, frescos y congelados, que se exporten o puedan exportarse a los Estados Unidos de America,

CONSCIENTES de la labor beneficiosa y cooperativa que se llev6 a cabo en los terminos del Memorando de Entendimiento de 1988 relativo a la inocuidad y calidad de los moluscos bivalvos exportados de los Estados Unidos Mexicanos a los Estados Unidos de America,

CONSIDERANDO las consultas tecnicas que han dado lugar a la elaboración y aplicación en los Estados Unidos Mexicanos de un programa sanitario eficaz para los moluscos bivalvos,

RECONOCIENDO que ninguna de las disposiciones del presente Memorando de Entendimiento menoscabara de manera alguna la responsabilidad y autoridad de la FDA, conforme a la sección 801 de la Ley Federal de Alimentos, Farmacos y Cosmeticos, de examinar cualquier producto alimenticio que se ofrezca para entrar en los Estados Unidos de America, y cuando resulte conveniente, rehusarle la entrada, y de acatar y hacer cumplir cualquier otra ley que administre la propia FDA,

OBSERVANDO que la FDA reconoce el Programa Mexicano de Sanidad de Moluscos Bivalvos (PMSMB) y considera que cumple adecuadamente con las pautas del Programa

Nacional Estadounidense de Sanidad de los Moluscos Bivalvos *(United States National Shellfish Sanitation Program,* NSSP, y que la COFEPRIS tiene la responsabilidad general con respecto al PMSMB y coordina la participacion de los Gobiernos de las Entidades Federativas Mexicanas en el Programa de los Moluscos Bivalvos,

Han acordado to siguiente:

ARTICULO I

Obj etivo

El presente Memorandum de Entendimiento tiene como objetivo establecer los lineamientos que deben aplicarse para asegurar que los moluscos bivalvos que se exporten de los Estados Unidos Mexicanos y se ofrezcan para la importacion en los Estados Unidos de America sean inocuos para el consumo humano y se recolecten, elaboren, transporten y rotulen conforme a los requisitos exigidos por la ordenanza modelo del NSSP y a los requisitos pertinentes de la Ley Federal de los Estados Unidos de America sobre Alimentos, Farmacos y Cosmeticos (U.S. *Federal Food, Drug and Cosmetic Act),* la Ley del Servicio Sanitario Publico de los Estados Unidos de America (U.S. *Public Health Service Act),* la Ley de los Estados Unidos de America sobre Empaquetado y Etiquetado Justos (U.S. *Fair Packaging and Labeling Act),* y el Titulo 21 del Codigo de los Reglamentos Federales de los Estados Unidos de America *(United States Code of Federal Regulations).*

ARTICULO II

Defmiciones

Para los propositos de este Memorandum de Entendimiento los terminos que a continuacion se detallan tendran el significado siguiente:

1. Por aprobado se entiende la clasificacion que se emplea para senalar cuales son las zonas de cria donde se permite la recolecta de moluscos bivalvos para su comercializacion directa.

2. Por acuicultura se entiende la cria, en zonas naturales o artificiales, de semillas o de moluscos bivalvos en concha que ya no esten en la fase de semilla.

3. Por archivo central se entiende el lugar unico donde la COFEPRIS guarda copias de toda la informacion, datos, informes y mapas relativos al NSSP.

4. Por lote de moluscos bivalvos en concha se entiende un conjunto a granel o en envases de moluscos bivalvos en concha correspondiente a no mas de un dia de cosecha, procedente de una sola zona de cultivo definida y recolectado por un colector o por mas.

5. Por Tote de moluscos bivalvos desconchados se entiende un conjunto de envases de moluscos bivalvos separados de las conchas, obtenido de no mas de un dia de cosecha, procedente de una Bola zona de cultivo definida, producido en las condiciones mas uniformes posibles e identificado por una sepal o marca comun colocada en cada envase.

6. Por biotoxinas marinas se entiende cualquier compuesto venenoso producido por microorganismos marinos y acumulado en los moluscos bivalvos en concha.

7. Por Programa Mexicano de Sanidad de Moluscos Bivalvos (PMSMB) se entiende el programa de control reglamentario de los Estados Unidos Mexicanos, dirigido a asegurar, por la aplicaci6n de las medidos de control consignadas en el NSSP, la inocuidad de los moluscos bivalvos destinados a la exportaci6n a los Estados Unidos de America.

8. Por molusco bivalvo se entiende todas las especies comestibles, obtenidas por acuicultura, de ostiones, almejas, mejillones y escalopas enteras o en partes; con o sin conchas, frescos o congelados, enteros o en partes.

9. Por Programa Nacional Estadounidense de Sanidad de los Moluscos Bivalvos *(United States National Shellfish Sanitation Program,* NSSP) se entiende el programa cooperativo para velar por la inocuidad y calidad de los moluscos bivalvos destinados al consumo humano que se lleva a cabo entre estados (estadounidenses o no), la FDA y la industria. Las pautas para velar por la inocuidad y calidad de los moluscos bivalvos se consignan en la Ordenanza Modelo del NSSP (NSSP *Model Ordinance).*

10. Por patrullaje se entiende el control activo de la recolecta de moluscos bivalvos para asegurar que s6lo se recolecten, elaboren y envien los que procedan de las zonas aprobadas.

11. Por confinamiento se entiende la transferencia de moluscos bivalvos en concha de unas zonas no aprobadas a las aprobadas, con el fin de reducir los pat6genos (medidos por el grupo indicador de las bacterias coliformes) o las sustancias venenosas o daninas que se hallen en los moluscos bivalvos en concha, haciendo use del ambiente natural como medio de depuraci6n.

12. Por informes de inspecci6n sanitaria se entiende los informes evaluativos acerca de todos los factores medioambientales, incluidas las fuentes actuales y posibles de contaminaci6n, que puedan tener efectos sobre la calidad del agua en una zona de cria de moluscos bivalvos.

13. Por moluscos bivalvos en concha se entiende los moluscos bivalvos vivos en sus conchas.

ARTICLE III

Responsabilidades de las Partes

A. LAS OBLIGACIONES DE LA COFEPRIS

1. Ejercer la coordinacion y puesta en practica generales del PMSMB.

2. La COFEPRIS se propone:

a. Ejercer los controlas juridicos, administrativos, sanitarios y de inocuidad y calidad con respecto a los moluscos bivalvos destinados a la exportacion a los Estados Unidos de America por procesadores mexicanos autorizados.

b. Velar por que el PMSMB se ajuste al NSSP, inclusive en to siguiente, pero no limitandose a:

i. clasificar las aguas de cria de los moluscos bivalvos.

ii. preparar informes de inspeccion sanitaria y guardar los mismos, asi como todos los datos conexos, en un archivo central.

iii. actualizar, de forma anual y trienal, los informes de inspeccion sanitaria, para asegurar que cads zona de cria de moluscos bivalvos tenga su debida clasificacion.

iv. aprobar y supervisar las operaciones de recolecta y confinamiento y velar por que los moluscos bivalvos se identifiquen y etiqueten conforme al NSSP.

v. restringir y controlar la recolecta de moluscos bivalvos en las zonas de cria no aprobadas, y tomar medidas coercitivas contra las personas o las empresas que hagan la recolecta de moluscos bivalvos en dichas zonas.

vi. prohibir la recolecta de moluscos bivalvos en zonas de cria en emergencias que causen contaminacion, y rescindir esas prohibiciones cuando los datos de la calidad del agua o los analisis de las biotoxinas marinas demuestren que dichas zonas satisfacen los criterion de aprobacion del NSSP.

vii. retirar los moluscos bivalvos que no sean aptos para el consumo, cuando el procesador responsable incumpla su obligacion de retirarlos el mismo del mercado.

viii. conseguir que en el PMSMB participen laboratorios acreditados que se ajusten al NSSP.

ix. inspeccionar a los procesadores que elaboran moluscos bivalvos de acuicultura, frescos o congelados, para exportarlos a los Estados Unidos de America, a fin de asegurarse de que cumplen con los controles del NSSP.

x. autorizar a procesadores que exporten a los Estados Unidos de America moluscos bivalvos de acuicultura, frescos o congelados, conforme al NSSP, para que figuren en la Lista Interestatal de la FDA de Procesadores Autorizados de Moluscos Bivalvos *(Interstate Certified Shellfish Shippers List,* ICSSL).

xi. por medio del Formulario FD-3038, Autorizacion de los Procesadores de Moluscos Bivalvos *(Shellfish Dealer Certification),* notificar a la FDA el nombre, la direccion y el numero de autorizacion del PMSMB de los procesadores autorizados a que exporten a los Estados Unidos de America.

xii. invalidar la autorizacion de todo procesador:

- cuyas operaciones no esten de conformidad con el NSSP.

- que distribuya moluscos bivalvos recolectados en zonas no aprobadas.

- que distribuya moluscos bivalvos que por otras causas no esten de conformidad con las exigencias de la Ley Federal de los Estados Unidos de America sobre Alimentos, Farmacos y Cosmeticos, la Ley del Servicio Sanitario Piublico de los Estados Unidos de America, la Ley de los Estados Unidos de America sobre Empaquetado y Etiquetado Justos o el Titulo 21 del Codigo de los Reglamentos Federales de los Estados Unidos de America.

- que no retire del mercado los moluscos bivalvos acerca de los cuales se haya llegado a la conclusion de que no son aptos para el consumo humano.

xiii. asegurarse de que cada envase en un lote de moluscos bivalvos autorizado para la exportacion a los Estados Unidos de America este etiquetado debidamente conforme al NSSP.

xiv. guardar un archivo central de toda la documentacion del PMSMB, incluida la version en ingles de todos los informes de inspeccion sanitaria, patrullaje y analisis de laboratorio, y permitir que la FDA tenga acceso a ella, previa solicitud.

xv. proporcionar a los organismos federales y estatales a cargo del PMSMB, los informes evaluativos, las interpretaciones, la informacion de laboratorio relativa al programa de garantia de la calidad y demas

informacion acerca del programa sobre los moluscos bivalvos proveniente de la FDA.

xvi. por to menos una vez al ano, examinar el nivel de conformidad con el NSSP y resumir los resultados en un informe escrito, proporcionando a la FDA anualmente una traducci6n al ingles del mismo.

xvii. proporcionar informaci6n a la FDA acerca de los peligros efectivos o posibles para la salud pdblica de los moluscos bivalvos destinados a la exportacion a los Estados Unidos de America.

xviii. previa solicitud de la FDA, organizar viajes por los Estados Unidos Mexicanos de los funcionarios evaluadores de la FDA, efectuar inspecciones conjuntas con estos y proporcionarles transporte durante su estancia en los Estados Unidos Mexicanos.

c. Permitir que los moluscos bivalvos que elaboren los procesadores autorizados por el PMSMB para la exportaci6n a los Estados Unidos de America se recolecten unicamente en zonas de cria aprobadas por la COFEPRIS con el asentimiento de la FDA.

d. En el plazo de 30 dias del recibo de una notificacion escrita por la FDA acerca de cualquier deficiencia observada con respecto a to dispuesto en el NSSP, redactar por escrito un Plan de Acci6n Correctiva y presentarlo a la FDA para el examen y asentimiento de esta. Si ese Plan no se redacta en dicho plazo, la FDA tomara las medidas pertinentes para evitar que los moluscos bivalvos de los Estados Unidos Mexicanos entren en los Estados Unidos de America, entre ellas, retirar a los procesadores mexicanos de la ICSSL. Esas medidas permaneceran en efecto mientras no se corrijan todas las deficiencias del PMSMB con respecto a to dispuesto en el NSSP y mientras la FDA no haya llegado a la conclusion de que el PMSMB se ajusta al NSSP.

3. La COFEPRIS pods nombrar a un funcionario de evaluacion de laboratorios para:

a. Acreditar los laboratorios participantes en el PMSMB.

b. Evaluar peri6dicamente los laboratorios acreditados para el PMSMB, a fin de verificar que esten de conformidad con el NSSP y que observen los debidos procedimientos de laboratorio para el aseguramiento de la calidad.

c. Llevar a cabo un programa de vigilancia de las biotoxinas marinas en las zonas de cria donde se recolecten moluscos bivalvos para la exportaci6n a los Estados Unidos de America.

d. Llevar a cabo un programa de muestras divididas entre los laboratorios participantes en el PMSMB, para evaluar la uniformidad de sus practicas microbiol6gicas.

e. Notificar a la FDA acerca de los laboratorios que no se ajusten a to dispuesto por el NSSP.

f. Impedir que los laboratorios que no se ajusten a to dispuesto por el NSSP participen en el PMSMB.

4. La COFEPRIS debera actualizar la Ordenanza Modelo del PMSMB para que sea congruente con las revisiones publicadas de la Ordenanza Modelo del NSSP. La COFEPRIS facilitara una versi6n en ingles de todas las actualizaciones, para el examen y asentimiento de la FDA.

5. Toda transferencia de responsabilidades de la COFEPRIS a otra autoridad debera notificarse a la FDA en un plazo de 30 dias. Dicha transferencia de responsabilidades podria requerir otra evaluaci6n del PMSMB por parte de la FDA.

6. Los Gobiernos de las Entidades Federativas Mexicanas que participen en el PMSMB son igualmente responsables de asegurar la inocuidad y calidad de los moluscos bivalvos exportados a los Estados Unidos de America.

B. LAS OBLIGACIONES DE LA FDA

La FDA se propone:

1. Aceptar a los Estados Unidos Mexicanos como participantes en el NSSP, la Conferencia Interestatal de Sanidad de Moluscos Bivalvos *(Interstate Shellfish Sanitation Conference,* ICSSL), los programas cooperativos de investigaci6n, los seminarios, los cursos de capacitaci6n y otras actividades del NSSP, y que la COFEPRIS autorice la incorporacibn de procesadores mexicanos a la ICSSL de la FDA.

2. Publicar los nombres, direcciones y niumeros de autorizaci6n de las empresas mexicanas autorizadas por la COFEPRIS en la publicaci6n mensual de la ICSSL, al recibo del Formulario FD-3038.

3. Facilitar capacitaci6n y asistencia t6cnica a la COFEPRIS, siempre y cuando haya fondos y personal disponibles para esos fines.

4. Informar a la COFEPRIS de las razones para la detenci6n de cualquier envio de moluscos bivalvos de los Estados Unidos Mexicanos.

5. Participar con la COFEPRIS en evaluaciones conjuntas del PMSMB, para averiguar en que medida se ajusta a los requisitos del NSSP y a las obligaciones consignadas en el presente Memorandum de Entendimiento. La FDA sufragara los gastos de viaje de ida y vuelta entre los Estados Unidos de America y los Estados Unidos Mexicanos y los viaticos de los evaluadores de la FDA mientras se encuentren en los Estados Unidos Mexicanos.

6. Notificar a la COFEPRIS de las deficiencias observadas con respecto a to dispuesto en el NSSP, y solicitar a la COFEPRIS que presente por escrito, en el plazo de 30 dias, un Plan de Accion Correctiva a la FDA para su examen y asentimiento. Si el Plan no se elabora en dicho plazo o si las deficiencias no se corrigen conforme al Plan, la FDA tomara las medidas pertinentes para evitar que los moluscos bivalvos de los Estados Unidos Mexicanos entren en los Estados Unidos de America, entre ellas, retirar a los procesadores mexicanos de la ICSSL. Si se presenta una amenaza grave para la salud piiblica, el plazo de 30 dias puede acortarse o eliminarse. Las medidas de la FDA permaneceran en vigor hasta que todas las deficiencias con respecto al NSSP se hayan corregido y la FDA haya llegado a la conclusion de que el PMSMB se ajusta al NSSP.

7. Retirar a procesadores mexicanos especificos de la ICSSL cuando la FDA o COFEPRIS llegue a la conclusion de que esos procesadores no cumplen con el NSSP o cuando su producto represente un peligro inminente para la salud.

8. Informar a COFEPRIS acerca de toda transferencia de responsabilidades de la FDA a otra autoridad federal, en el plazo de 30 dias a partir de la fecha de la transferencia.

ARTICULO IV

Intercambio de Informacion Tecnica

Las Partes se proponen intercambiar conocimientos tecnicos; proporcionarse asistencia, e intercambiar informaci6n, la cual debera estar redactada en idioma ingles. En esa colaboraci6n se podran incluir, mas no se limitaran a, los siguientes aspectos:

1. El intercambio de informaci6n acerca de las modificaciones propuestas y definitivas en el funcionamiento y los procedimientos del PMSMB, to que incluira, entre otros, los siguientes aspectos:

   a. metodos y procedimientos de muestreo.

   b. metodos de analisis.

   c. metodos de confirmaci6n.

   d. pautas administrativas, variaciones permisibles, normas para las especificaciones y nomenclatura.

   e. normas para referencia y

   f. procedimientos de inspeccion.

2. La notificaci6n escrita a la otra Parte de los cambios ocurridos en los funcionarios de enlace, en el plazo de 30 dias. El cambio de dichos funcionarios no alterara por to demas las disposiciones del presente Memorandum de Entendimiento.

3. La facilitación del intercambio de información entre la COFEPRIS y los organismos federales y estatales estadounidenses que tengan que ver con la introducción y proliferación de los organismos exóticos que pudieran portar los moluscos bivalvos mexicanos.

ARTICULO V

Funcionarios de enlace

Para el adecuado seguimiento de las actividades de cooperación derivadas del presente Memorandum de Entendimiento, las autoridades responsables seran:

A. De la COFEPRIS:

Director(a) General de Control Sanitario de Productos y Servicios
Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)
Avenida Monterrey N° 33
Col. Roma C.P. 06700
Del. Cuauhtemoc
Mexico, DR, Estados Unidos Mexicanos
Telefono 011 52 55 5080, ext. 1254, 1259, 1230

B. De la FDA:

Director, Office of Seafood
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5 100 Paint Branch Parkway (HFS-400)
College Park, MD 20740
United States of America
Telefono 01301436-2300

ARTICULO VI

Disposiciones Finales

El presente Memorandum de Entendimiento entrara en vigor a partir de la fecha de su firma y tendra una duración de cinco (5) anos, prorrogables mediante consentimiento escrito de las partes.

Las partes se proponen evaluar este Memorandum de Entendimiento durante el periodo de cinco afos y podra ser modificado por mutuo consentimiento, formalizado a traves de comunicaciones escritas, en las que se especifique la fecha de su entrada en vigor.

Las actividades emprendidas con arreglo al presente Memorandum de Entendimiento se efectuaran conforme a las leyes y los reglamentos de los Estados Unidos Mexicanos y de los Estados Unidos de America, y dependeran de la disponibilidad de personal, recursos y fondos consignados.

El presente Memorando no se propone generar obligaciones conforme al derecho internacional u otras leyes.

En fe de to cual los infrascritos, habiendo sido autonzados debidamente por sus organismos respectivos, han firmado el presente Memorando de Entendimiento.

Firmado en la Ciudad de San Antonio, Texas, el 18 de junio de 2003, en cuadruplicado en los idiomas espanol e ingles, siendo ambos textos igualmente autenticos.

POR EL DEPARTAMENTO DE SALUD Y SERVICIOS HUMANOS DE LOS ESTADOS UNIDOS DE AMERICA

MARK B. MC CLELLAN

Comisionado de la Administracion de Alimentos y Farmacos

De la Administracion de Alimentos y Farmacos

POR LA SECRETARIA DE SALUD DE LOS ESTADOS UNIDOS MEXICANOS

LIC. ERNESTO ENRIQUEZ RUBIO

Comisionado Federal para la Proteccion contra Riesgos Sanitarios

De la Comision Federal para la Proteccion contra Riesgos Sanitarios

[FR Doc. 03–20246 Filed 8–8–03; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: National Health Service Corps (NHSC) Travel Request Worksheet, Non-Federal Personnel—In Use Without Approval

The National Health Service Corps (NHSC), of the HRSA's Bureau of Health Professions (BHPr), is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The NHSC (sections 331–338 of the Public Health Service Act) collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, the NHSC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends.

The Travel Request Worksheet is used by NHSC Scholarship Program recipients to receive travel funds from the Federal Government to perform pre-employment interviews at sites on the Approved Practice List. The travel approval process is initiated when the scholar notifies the NHSC's In-Service Support Branch or the respective Bureau of Prisons, Indian Health Service, or Immigration and Naturalization Service recruitment office of an impending interview at one or more NHSC approved practice sites.

The Travel Request Worksheet is also used to initiate the relocation process after an NHSC scholar has successfully match to an approved practice site. Upon receipt of the Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the NHSC contractor whether to authorize the funding for the relocation.

Estimates of annualized reporting burden are as follows:

Type of respondent	Number of respondents	Responses per respondent	Hours per response (minutes)	Total burden hours
Health Care Professionals	311	2	4	41

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Eydt, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number 202–395–6974.

Dated: August 5, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–20382 Filed 8–8–03; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Federal Housing Enterprise Oversight

Strategic Plan

AGENCY: Office of Federal Housing Enterprise Oversight, HUD.

ACTION: Solicitation of comments for updating the Strategic Plan.

SUMMARY: The Office of Federal Housing Enterprise Oversight (OFHEO) is soliciting comments on its revised Strategic Plan. In accordance with the requirements of the Government Performance and Results Act of 1993 that agencies update their Strategic Plans every three years, OFHEO has developed its draft 2003–2008 Strategic Plan and is soliciting the views and suggestions of those entities potentially affected by or interested in the plan. OFHEO's draft Strategic Plan, for FY 2003–2008, may be viewed on the OFHEO Web site at *www.ofheo.gov/OFHEOReports.asp*.

DATES: Written comments regarding the draft Strategic Plan may be received through August 27, 2003.

ADDRESSES: All comments concerning the notice should be addressed to: Susan S. Jacobs, Associate Director, Office of Strategic Planning and Management, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Third Floor, Washington, DC 20552. Comments may also be submitted via electronic mail to: *StrategicPlan@ofheo.gov*. OFHEO requests that written comments submitted in hard copy also be accompanied by the electronic version in MS Word or in portable document format (PDF) on 3.5'' disk.

FOR FURTHER INFORMATION CONTACT: Susan S. Jacobs, Associate Director, Office of Strategic Planning and Management, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Third Floor, Washington, DC 20552, telephone (202) 414–3821 (not a toll-free number). The telephone number for the Telecommunications Device for the Deaf is: (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Office of Federal Housing Enterprise Oversight (OFHEO) is charged by Congress, as established in Title XIII of the Housing and Community Development Act of 1992, known as the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, with the mandate of overseeing the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation, Fannie Mae and Freddie Mac (the ''Enterprises'').

Three years ago, OFHEO adopted a Strategic Plan covering FY 2000–2005. Section 306 of the Government Performance and Results Act of 1993 (GPRA), 31 U.S.C. 1115 *et seq.*, requires that agencies update and revise their Strategic Plans every three years. OFHEO has drafted a new plan for FY 2003–2008 that describes the agency's mission, strategic goals, and strategies to achieve them. This plan will provide a framework for the years ahead. OFHEO uses its Strategic Plan to guide each year's performance goals, which are described in OFHEO's Annual Performance Plans. They may be viewed