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 Sankyo Pharma has requested that approval of this application be withdrawn because the product is not being marketed, thereby waiving its opportunity for a hearing.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