DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Referral of Morphine Sulfate for the Conduct of Pediatric Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the referral of morphine sulfate to the Foundation for the National Institutes of Health (the Foundation) for the conduct of pediatric studies. FDA referred the drug to the Foundation on September 29, 2003, and is publishing this notice of the referral in accordance with the Best Pharmaceuticals for Children Act (BPCA).

FOR FURTHER INFORMATION CONTACT: Terrie Crescenzi, Office of Pediatric Therapeutics (HFG–2), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–44, Rockville, MD 20857, 301–827–9218.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 4 of the BPCA (Public Law 107–109), FDA is announcing the referral to the Foundation of the written request for the conduct of pediatric studies for the use of intravenous (IV) morphine sulfate. Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the exclusivity incentive program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

The BPCA established additional mechanisms for obtaining information on the safe and effective use of drugs in pediatric patients. Specifically, section 4 of the BPCA amends section 505A(d) of the act to create a referral process to obtain studies for drugs that have patent or exclusivity protection, but for which the sponsor has declined to conduct the pediatric studies in response to a written request by FDA. Under section 4 of the BPCA, if the Secretary of Health and Human Services (the Secretary) determines that there is a continuing need for the pediatric studies described in the written request and the sponsors of the products with patent or exclusivity protection have declined to conduct the studies, the Secretary shall refer the drug to the Foundation, established under section 499 of the Public Health Service Act (42 U.S.C. 290(b)), for the conduct of the pediatric studies described in the written request (21 U.S.C. 355a(d)(4)(B)(i)). In addition, the BPCA requires public notice of the name of the drug, name of the manufacturer, and indications to be studied pursuant to the referrals (21 U.S.C. 355a(d)(4)(B)(ii)).

In accordance with section 4 of the BPCA, FDA is announcing that it has referred the written request for pediatric studies for the IV use of morphine sulfate to the Foundation. On March 28, 2003, FDA issued a written request for pediatric studies to Faulding Pharmaceutical Co. and Ligand Pharmaceuticals, the holders of approved applications for morphine sulfate that have market exclusivity. The studies described in the written request were for the indication of moderate-to-severe pain in the pediatric population. Not later than 180 days after receiving the written request, Faulding Pharmaceutical Co. and Ligand Pharmaceuticals declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the IV use of morphine sulfate in the pediatric population. Consistent with the provisions of the BPCA, on September 30, 2003, FDA referred to the Foundation the written request for the conduct of the pediatric studies for IV morphine sulfate.

Dated: December 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–17 Filed 1–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8005]

Memorandum of Understanding Between the Food and Drug Administration and the Central Science Laboratory, Department of Environment, Food and Rural Affairs of the United Kingdom Concerning Analytical Methods in Support of Food Safety

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Central Science Laboratory, Department of Environment, Food and Rural Affairs of the United Kingdom. The purpose of this MOU is to provide a framework for developing a common approach to analytical methods in support of food safety in relation to the protection of public health and international trade.

DATES: The agreement became effective October 28, 2003.

FOR FURTHER INFORMATION CONTACT: Elizabeth Calvey, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1981.

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

Dated: December 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

MEMORANDUM OF UNDERSTANDING

BETWEEN

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

AND

CENTRAL SCIENCE LABORATORY
DEPARTMENT OF ENVIRONMENT, FOOD AND RURAL AFFAIRS
OF THE UNITED KINGDOM

The United States Food and Drug Administration (USFDA), Department of Health and Human Services (DHHS) and the United Kingdom Central Science Laboratory (CSL), Department of Environment, Food and Rural Affairs (DEFRA) (collectively "the Participants") recognizing that

The scientific laboratories underpinning the USFDA/DHHS and the CSL/DEFRA are faced with common technical challenges in providing surge capacity and speed-of-response for analytical services;

New challenges are likely to arise in the areas of molecular diagnostics, veterinary drugs, and food supplements;

USFDA is charged with the enforcement of the Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301), and is the lead United States regulatory agency responsible for assuring, among other things, the safety of the nation's food supply and the safety and effectiveness of animal drugs, animal food additives, and animal feed ingredients;

CSL plays a major role in food safety in the UK for Government customers by undertaking analyses and monitoring (supported by research and development) to ensure the safety and quality of foods and animal feeds;

Through the joint efforts of USFDA and CSL, new approaches can be identified and developed in the areas of analytical quality assurance and food safety thus working to the mutual benefit of both organizations and towards the achievement of their objectives; and

A more formal relationship between the Participants that permits regular exchange of scientists, training, technology transfer and exchange of scientific literature would greatly enhance the capabilities of the Participants to carry out their responsibilities in consumer protection with regard to issues of food safety and quality and animal health

Have reached the following understanding.

ARTICLE 1
Purpose

This Memorandum of Understanding (MOU) is intended to provide a framework for developing a common approach to analytical methods in support of food safety in relation to the protection of public health and international trade.

Specifically, the MOU has the following objectives:

a) Information exchange on priorities for future methods development;
b) Exchange of technical staff for training;
c) Intellectual property framework for exchange of analytical protocols; and
d) Annual review of analytical methods at the senior staff level.

ARTICLE 11
Activities

A. In order to achieve fully the objectives of this MOU, USFDA and CSL intend to take the following actions:

1) Initiate and maintain a dialogue on matters of food safety and quality, and
2) Participate in the execution of on-going programs, projects, and related activities that are satisfactory to the Participants, whenever financial and other arrangements can be made.

B. In case of joint projects discussed in point A.2 of the present Article, the Participants intend to develop prior to starting the work, on a case-by-case basis and in accordance with the existing regulations, a specific written agreement setting up the arrangements related to the planned activity. These individual project agreements should, as necessary, address technical, security, and financial aspects, including intellectual property rights and identifying the responsibilities of the Participants.

ARTICLE 111
Responsibilities of the Participants

A. USFDA and CSL each intend to designate professional technical staff in their respective agencies as coordinators with responsibility for facilitating and coordinating the various areas of collaboration identified by the Participants.

B. Each Participant is to be responsible for its own personnel in activities undertaken pursuant to this MOU

C. When staff members from USFDA or CSL participate for brief periods in programs, projects or activities implemented by the other Participant, the Participants intend to develop prior to starting the work, on a case-by-case basis and in accordance with the existing regulations, a specific written agreement similar to the agreement described in paragraph B of Article 2. These agreements should include the conditions of co-operation to be provided by the staff-member and the terms under which USFDA and CSL are authorizing its staff member to participate. The host organization should assist as much as possible in meeting the personal and professional needs of the visitor, including providing or helping to provide access to institutional facilities.

E. When required, meetings between USFDA and CSL coordinators or their authorized

representatives are expected to take place to permit evaluation of progress in collaborative projects and ensure co-ordination in the development of future programs and policies.

ARTICLE 1V
Protection of Data, Information and Intellectual Property

A. The Participants expect that most of the information exchanged under this MOU may be provided in a form appropriate for public dissemination under the laws of both Participants. Information that is not appropriate for public dissemination should be shared according to the procedures and policies of the Participants only as permitted by the laws of the participants.

B. Under this MOU, the Participants should consult with one another and mutually agree regarding the following communications:

1) the publication of any information transmitted by the other Participant;
2) the transmission of any results to other government agencies or to persons, bodies and undertakings not engaged, in the UK or US, in research or production justifying access to such results; or
3) the dissemination of the information in public fora.

The collaboration of the other Participant should be mentioned in publications or in public presentations.

C. The applicable right to inventions, whether or not patentable, made or conceived when carrying out any activity under this MOU belongs to the employer of the inventor. In case of inventions made or conceived by more than one inventor having different employers, the invention is owned in common by the employers. If a co-owner of an invention elects not to pursue patent protection for that invention, it should promptly inform the other co-owner of such election, so as not to prejudice the other's ability to pursue patent protection for the invention on its own behalf.

D. Unless there is a specific written agreement established under Article 111.C, the co-owners may exploit, or have the inventions and patents referred to in paragraph C of the present Article exploited, based upon mutual agreement or, if the Participants cannot agree, each co-owner may independently exploit the invention. The Participants may agree to consolidate ownership of any invention with one Participant to exploit the invention through a license agreement. In addition, any Participant seeking patent protection for such an invention should grant a Power of Attorney and the right to review any patent office communications to the co-owning Participant for any patent applications directed to an invention made or conceived under this MOU.

E. The provisions of paragraphs C and D of the present Article shall remain valid after the expiry of this MOU as long as the inventions are protected by a patent or by secrecy.

ARTICLE V
Source of Funding

Each Participant to this MOU intends to fund its own activities subject to the availability of appropriated funds, personnel and other resources. Any exchange of information or any other activity under this MOU is to be performed in accordance with applicable laws and regulations, policies and programs of the Participants.

ARTICLE V1
Settlement of Disputes

The Participants should strive to resolve by mutual decision any disputes that arise from the interpretation or application of this MOU.

ARTICLE V11
Liaison Officers

Liaison officers will be as follows:

A. For CSL

Professor John Gilbert
Research Director (Food)
Central Science Laboratory
Department of Environment, Food, and Rural Affairs
Sand Hutton, York Y041 1LZ
United Kingdom
Telephone: +44 (0) 1904 4624 24

B. For FDA

Office of Science
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway (HFS-006)
College Park, MD 20740
Telephone: 301-436-1981

Director, Division of Residue Chemistry
Center for Veterinary Medicine
Food and Drug Administration
8401 Muirkirk Road (HFV-510)
Laurel, MD 20708
Telephone: 301-827-8167

Deputy Director, Division of Field Science
Office of Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane (HFC-140)
Rockville, MD 20857
Telephone: 301-827-1026

ARTICLEV11
Duration

Activities under this MOU commence upon signatures of both Participants and continue in effect for a period of five years. The Participants agree to evaluate the agreement during the five-year period. It may be extended or modified by written consent of the Participants. Either Participant, upon 30-days written notice to the other Participant, may terminate this MOU.

Signed at Washington, D.C., in duplicate, this twenty-ninth day of October 2003.

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

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

FOR THE CENTRAL SCIENCE LABORATORY
DEPARTMENT OF ENVIRONMENT, FOOD AND RURAL AFFAIRS
OF THE UNITED KINGDOM

Professor M. Roberts
Chief Executive

[FR Doc. 04–15 Filed 1–2–04; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1990D–0194]

Radioimmunoassay Analysis of Hair to Detect the Presence of Drugs of Abuse; Revocation of Compliance Policy Guide 7124.06

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the compliance policy guide (CPG) entitled ''Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse (CPG 7124.06).'' This CPG no longer reflects current agency policy.

DATES: The revocation is effective January 5, 2004.

ADDRESSES: Submit written requests for single copies of CPG 7124.06 to the Division of Compliance Policy (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, FAX 301–827–0482.

A copy of the CPG may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued the CPG entitled ''Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse (CPG 7124.06)'' on May 31, 1990. The CPG stated that the use of radioimmunoassay (RIA) to analyze hair for the presence of drugs of abuse lacked scientific evidence of its safety and effectiveness, as defined in 21 CFR 860.7. Accordingly, the CPG indicated that approved premarket approval applications (PMAs) were necessary before commercially distributing these types of devices.

Since publication of this CPG, more than 88 scientific articles on drugs of abuse testing in hair have been published in the peer-reviewed scientific literature. There has been extensive discussion about the analytical performance, the clinical parameters, and sources of error and testing differences for this technology compared to other technologies. FDA has reviewed a number of hair tests and found these to be substantially equivalent to predicate devices measuring drugs of abuse in other matrices. Given these scientific developments and product clearances,