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.

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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.