Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 8, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–8531 Filed 4–14–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Application; Ceftiofur

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Pharmacia &Upjohn, Co. The supplemental NADA provided revised susceptibility information for equine pathogens listed in the clinical microbiology section of labeling for ceftiofur sodium sterile powder for injection and added interpretive criteria. The applicable section of the regulations did not require amendment.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.gov.*

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn, Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplement to NADA 140–338 which provides for the veterinary prescription use of NAXCEL (ceftiofur sodium) Sterile Powder for Injection. The supplemental NADA provided updated susceptibility data for equine respiratory pathogens listed in the clinical microbiology section of labeling and added the National Committee for Clinical Laboratory Standards' interpretive criteria for equine isolates. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that this supplemental NADA is approved as of February 27, 2004. The basis of approval is discussed in the freedom of information (FOI) summary.

In accordance with the FOI provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 19, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–8513 Filed 4–14–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0158]

Referral of ZONEGRAN (Zonisamide), WELLBUTRIN and ZYBAN (Bupropion), and RENAGEL (Sevelamer) 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 ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer) to the Foundation for the National Institutes of Health (the Foundation) for the conduct of pediatric studies. FDA referred these drugs to the Foundation on November 14, 2003, and is publishing this notice of the referrals.

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7777.

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 requests for the conduct of pediatric studies for ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer). 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.

In accordance with section 4 of the BPCA, FDA is announcing that it has referred the written request for pediatric studies for ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer) to the Foundation. On July 3, 2002, FDA issued a written request for pediatric studies to Elan Pharmaceuticals, the holder of approved applications for ZONEGRAN (zonisamide) that have market exclusivity. The studies described in the written request were for adjunctive therapy in the treatment of partial seizures in the pediatric population. Elan Pharmaceuticals declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of ZONEGRAN (zonisamide) in the pediatric population.

On July 2, 2002, FDA issued a written request for pediatric studies to GlaxoSmithKline, the holder of approved applications for orally

administered WELLBUTRIN and ZYBAN (bupropion) that have market exclusivity. The studies described in the written request were for the indications of depression and smoking cessation in the pediatric population. GlaxoSmithKline declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of WELLBUTRIN and ZYBAN (bupropion) in the pediatric population.

On July 3, 2002, FDA issued a written request for pediatric studies to GelTex Pharmaceuticals, the holder of approved applications for RENAGEL (sevelamer) that have market exclusivity. The studies described in the written request were for the indication of hyperphosphatemia in the pediatric population. GelTex Pharmaceuticals declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of RENAGEL (sevelamer) in the pediatric population.

Consistent with the provisions of the BPCA, on November 14, 2003, FDA referred to the Foundation the written requests for the conduct of the pediatric studies for ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer).

Dated: April 7, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8514 Filed 4–14–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8006]

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 Maritime Affairs and Fisheries of the Republic of Korea Covering the Safety and Quality of Fresh and Frozen Aquacultured Molluscan Shellfish Exported From the Republic of Korea 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 Maritime Affairs and Fisheries of the Republic of Korea. 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 Republic of Korea. The purpose of the MOU is to establish the set of guidelines to be implemented for assuring that molluscan shellfish exported from the Republic of Korea 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 and the applicable requirements of the U.S. Federal Food and 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.

DATES: The agreement became effective October 28, 2003.

FOR FURTHER INFORMATION CONTACT: Paul W. Distefano, Center for Food Safety and Applied Nutrition (HFS–417), Food and Drug Administration, 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: March 24, 2004.

Jeffrey Shuren,

Assistant Commissioneer for Policy.

BILLING CODE 4160–01–S