Written comments and recommendations will be accepted from the public if received by the individuals designated below within 14 days from the date of this publication. (**Note:** An Emergency **Federal Register** Notice for this collection was published on March 19, 2004; however, due to a technical discrepancy with the material submitted to OMB which has since been corrected, OMB has requested that CMS republish the notice. All information below is identical to the material published on March 19th.)

Type of Information Collection Request: Reinstatement without change.

Title of Information Collection: Survey of States Performance Measurement Reporting Capability.

Form No.: CMS–10082 (OMB# 0938–0898).

Use: Because of the wide variability of Medicaid and SCHIP financing and service delivery approaches, there is little common ground from which to develop uniform reporting on performance measures by states. While CMS has decided on the first seven measures to be used, the ability of states to calculate those measures using HEDIS directly or HEDIS specifications (*e.g.*, when calculating measures from fee-for-service claims data) is highly variable. Current efforts are focused on assessing the capability of each state to report on the selected measures and on helping states to make necessary adjustments in order to be able to report measures uniformly so that state-to-state comparisons can be made. To accomplish this, states will be requested to report available numerator and denominator data for the seven core HEDIS measures via a survey instrument created for this purpose. The data will be requested for each state's Medicaid and SCHIP programs by delivery system.

Frequency: Once.

Affected Public: State, local, and tribal government.

Number of Respondents: 51.

Total Annual Responses: 51.

Total Annual Hours: 2,360.

We have submitted a copy of this notice to OMB for its review of these information collections.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Jburke3@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–4194.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, within 14 days of publication of this notice:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, Fax Number: (410) 786–0262, Attn: Melissa Musotto CMS–10082, and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Katherine T. Astrich, CMS Desk Officer 0938–0898.

Dated: April 8, 2004.

John P. Burke III,

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

[FR Doc. 04–8530 Filed 4–14–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–250–254 and CMS–1964]

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

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Request:* Extension of a currently approved collection.

Title of Information Collection: Medicare Secondary Payer Information Collection and Supporting Regulations in 42 CFR 411.25, 489.2, and 489.20.

Form Number: CMS–250 through CMS–254 (OMB# 0938–0214).

Use: Medicare Secondary Payer (MSP) is essentially the same concept known in the private insurance industry as coordination of benefits and refers to those situations where Medicare does not have primary responsibility for paying the medical expenses of a Medicare beneficiary. Medicare intermediaries and carriers must collect information to perform various tasks to detect and process MSP cases.

Frequency: On occasion and Other: One time.

Affected Public: Individuals or households, Business or other for-profit, and not-for-profit institutions.

Number of Respondents: 134,553,682.

Total Annual Responses: 134,553,682;

Total Annual Hours Requested: 1,114,839.

2. *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: Request for Review of Part B Medicare Claim and Supporting Regulations in 42 CFR 405.807.

Form No.: CMS–1964 (OMB# 0938–0033).

Use: This form is the preferred manner to enable appellants to request a Part B review by a carrier.

Frequency: Other: as needed.

Affected Public: Individuals or Households, and not-for-profit institutions.

Number of Respondents: 6,860,000.

Total Annual Responses: 6,860,000.

Total Annual Hours: 1,715,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch,

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