

conditions suggested in its proposed labeling; (2) lacks evidence consisting of adequate and well-controlled investigations that Deprenyl will have the effect it is represented to have in the NDA; (3) fails to contain bioavailability data required by § 320.21; (4) fails to contain information that establishes that the methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance and the drug product are adequate to preserve their identity, strength, quality, purity, stability, and bioavailability; and (5) does not contain the proposed labeling for the bulk drug substance and the packaged drug product. I also find that Discovery was not in compliance with FDA's CGMP regulations published at parts 210 and 211.

Therefore, under the Federal Food, Drug, and Cosmetic Act (section 505(d)) and under the authority delegated to me in 21 CFR 5.10, Discovery's request for a hearing is denied and approval of NDA 20-242 is denied.

Dated: February 28, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-8517 Filed 4-2-97; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

[HCFA-R-204]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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 the 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.

Type of Information Collection Request: New Collection; Title of Information Collection: Data Collection

for the Second Generation Social Health Maintenance Organization Demonstration; *Form No.:* HCFA-R-204; *Use:* The data collected under this effort will be used to support the operational and evaluation needs of the Congressionally-Mandated Second Generation of the Social Health Maintenance Organization Demonstration. *Frequency:* On occasion, Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 157,056; *Total Annual Responses:* 157,056; *Total Annual Hours:* 133,652.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov/regs/prdact95.htm>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 26, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97-8526 Filed 4-2-97; 8:45 am]

BILLING CODE 4120-03-P

[HCFA-R-203]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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.

Type of Information Collection Request: New Collection; Title of Information Collection: Data Collection Forms for a Project to Develop a Case-Mix Adjustment System for a National Home Health Prospective Payment Program; Form No.: HCFA-R-203; *Use:* The data collection from this form will support analysis of home health utilization patterns and develop predictive models of home health resource use. That will serve as the basis for a system to adjust payments for Medicare home health services for differences/changes in patient service needs; *Frequency:* On Occasion; *Affected Public:* Not-for-profit, Business or other for-profit; *Number of Respondents:* 893,629; *Total Annual Responses:* 893,629; *Total Annual Hours:* 52,156.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov/regs/prdact95.htm>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, 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 HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: March 11, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97-8525 Filed 4-2-97; 8:45 am]

BILLING CODE 4120-03-P

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 35, United States Code, as amended by the

Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Performance Outcome Demonstration Study—New

Through Titles VII and VIII programs, the Bureau of Health Professions provides both policy leadership and support for health professions workforce enhancement and educational

infrastructure development. An outcome-based performance measurement system is central to the ability of the Bureau to measure whether program support is meeting its national health workforce objectives, and to signal where program course correction is necessary.

In addition, the Government Performance and Results Act (GPRA) requires each agency to develop comprehensive strategic plans, to submit annual performance plans that set specific performance goals for each program activity, and to report annually on the actual performance achieved compared to the performance goals.

The Bureau of Health Professions has developed a comprehensive program which consists of cross-cutting indicators designed to capture the common activities across programs, cluster level indicators designed to capture common activities for programs with a similar focus, and program specific indicators designed to capture activities which are specific to selected individual programs. At the core of the Bureau's performance measurement system are four cross-cutting goals with respect to workforce quality, supply, diversity and distribution. External customer input was utilized to validate the Bureau's proposed outcomes and indicators, and to assist with a

preliminary assessment of the suitability of data sources. A pilot study of nine program sites within the Washington metropolitan area was completed to determine the availability of the data along with the clarity of the definitions and instructions. The results of the pilot indicate that these data can be collected from grantees.

A wider demonstration will be done to assess the ability of current grantees, in the second year of the project period or later, to supply the data without the benefit of a site visit and to further refine the definitions and instructions. Since data are collected by discipline, the estimate of burden hours per response is different for projects that involve a single discipline and projects that involve multiple disciplines.

It is expected that the data collection tool for the demonstration may be distributed through the Internet, as has been done for the grant application materials for these programs, and returned to the Bureau in the mail. However, when this data collection system is fully implemented, it is expected that the distribution and submission will be fully automated and that the data collection tool will be an interactive program which prompts respondents to report only those data relevant to their programs. Burden estimates are as follows:

Type of respondent	No. of respondents	Responses per respondent	Burden hours per response	Total burden hours
Projects involving a single discipline	400	1	8	3,200
Projects involving multiple disciplines	16	1	40	640
Total	416	1	9.2	3,840

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 27, 1997.

J. Henry Montes,

Director, Office of Policy and Information Coordination.

[FR Doc. 97-8449 Filed 4-2-97; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of Record of Decision and Statement of Findings on the Environmental Impact Statement on Reintroduction of the Mexican Wolf to its Historic Range in the Southwestern United States

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of record of decision.

SUPPLEMENTARY INFORMATION: Pursuant to regulations implementing the National Environmental Policy Act (40 CFR 1505.2), the Department of the Interior, Fish and Wildlife Service announces the availability of the Record of Decision and Statement of Findings on the Environmental Impact Statement

on Reintroduction of the Mexican Wolf to its Historic Range in the Southwestern United States.

The Record of Decision authorizes implementation of the Preferred Alternative (Alternative A) as set forth in the Final Environmental Impact Statement. As soon as practicable, the U.S. Fish and Wildlife Service will reintroduce Mexican gray wolves, classified as a nonessential experimental population, in eastern Arizona for the purpose of establishing a population of at least 100 wolves distributed throughout the Blue Range Wolf Recovery Area, which includes portions of western New Mexico. If feasible and necessary to achieve the population objective of 100 wolves, a subsequent reintroduction of Mexican gray wolves into the White Sands Wolf Recovery Area in southern New Mexico will be conducted.