

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