submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 15, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–33393 Filed 12–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 27 and 28, 2000, 8 a.m. to 5 p.m.

Location: Hilton, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sandra L. Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, or e-mail TITUSS@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 27, 2000, the committee will consider the safety and efficacy of new drug application (NDA) 20–914, Promem™ (metrifonate, Bayer Corp., Pharmaceutical Division), proposed to treat mild to moderate dementia of the Alzheimer's type. On January 28, 2000, the committee will consider the safety and efficacy of NDA 21–120, Novantrone® (mitoxantrone, Immunex Corp.) proposed to treat secondary progressive multiple sclerosis, including progressive relapsing disease.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 20, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 20, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 16, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–33395 Filed 12–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4461]

Withdrawal of Guidance Document on Selegiline Hydrochloride Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a guidance for industry entitled ''Selegiline Hydrochloride Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This guidance, which was issued in December 1995, is being withdrawn because it does not represent current agency thinking on in vivo bioequivalence (BE) and in vitro testing for selegiline hydrochloride.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on agency guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–857–5847.

SUPPLEMENTARY INFORMATION: FDA is withdrawing a guidance for industry entitled ''Selegiline Hydrochloride Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This guidance addresses BE and dissolution testing for selegiline. This guidance is being withdrawn because it does not include the appropriate acceptance criteria for parent selegiline in plasma. Based on a new understanding of the pharmacokinetics of selegiline hydrochloride developed since the publication of the selegiline guidance, FDA has been requesting applicants to demonstrate that the point estimate of the test to reference ratio for area under plasma concentration-time curve (AUC) and peak blood plasma concentration (Cmax) of the parent falls within 80 to 125 percent. These criteria have been used for the demonstration of bioequivalence of all selegiline tablets and capsules currently on the market. In addition, the guidance, which was issued in December 1995, includes information only on selegiline tablets and not selegiline capsules, which have been approved by FDA since the issuance of the guidance to be withdrawn.

The withdrawal of this guidance is part of a long-term effort in the Office of Generic Drugs (OGD) to review guidance documents on the development of generic drug products with the goal of identifying documents that need to be revised, reformatted, or withdrawn because they are no longer current (64 FR 36886, July 8, 1999). OGD hopes the guidance review process will result in guidances for industry that better reflect the current thinking of the agency on generic drug development and that will eliminate the need for drug-specific bioavailability (BA) and BE guidances. A guidance currently under development on BA and BE studies for orally administered drug products will serve as a core guidance on BA and BE once it has been finalized and will replace most product-specific guidances.

The agency welcomes comments on its efforts to review existing guidances related to the development of drug products and revise, reformat, or withdraw them, as appropriate. This information is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It does not create or confer any rights for or on any

person and does not operate to bind FDA or the public.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on agency guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–33396 Filed 12–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes 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 and draft instruments, 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: Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers, and Practitioners—(OMB 0915–0239)—Extension

Section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 specifically directs the Secretary to establish a national health care fraud and abuse data collection program for the reporting and disclosure of certain final adverse actions taken against health care providers, suppliers, and practitioners. A final rule was published October 26, 1999 in the **Federal Register** to implement the statutory requirements of section 1128E of the Social Security Act (The Act) as added by Section 221(a) of HIPAA. The Act requires the Secretary to implement the national health care fraud and abuse data collection program. This data bank is known as the Healthcare Integrity and Protection Data Bank (HIPDB). It contains the following types of information: (1) Civil judgments against a health care provider, supplier, or practitioner in Federal or State court related to the delivery of a health care item or service; (2) Federal or State criminal convictions against a health care provider, supplier, or practitioner related to the delivery of a health care item or service; (3) actions by Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, or practitioners; (4) exclusion of a health care provider, supplier, or practitioner from participation in Federal or State health care programs; and (5) any other adjudicated actions or decisions that the Secretary shall establish by regulations. Access to this data bank is limited to Federal and State Government agencies and health plans.

The estimated response burden is as follows:

Regulation citation	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
61.6, Errors & Omissions	1,200	1	1,200	[1] 25	500
61.6, Revisions/Appeal Status	1,000	1	1,000	[1] 75	1,250
61.7, Licensure actions:					
Disclosure by State Licensing Boards	1,836	22	40,400	[1] 75	50,500
Reporting By State Licensing Authorities	216	187	40,400	[1] 15	10,100
61.8, Reporting of State Criminal Convictions	54	13	700	[1] 75	875
61.9, Reporting of Civil Judgments	62	8	500	[1] 75	625
61.11, Reporting of Adjudicated Actions/Decisions	66	12	800	[1] 75	1,000
61.12, Access to Data (Queries/Self Queries):					
State Licensure Boards	1,000	75	75,000	[1] 5	6,250
State Certification Agencies	54	3	162	[1] 5	14
States/District Attorneys & Law Enforcement	2,000	25	50,000	[1] 5	4,166
State Medicaid Fraud Units	47	50	2,350	[1] 5	196
Health Plans	2,500	400	1,000,000	[1] 5	83,333
Health Care Providers, Suppliers and Practitioners (self query)	60,000	1	60,000	[1] 25	25,000
Entity Registration	5,000	1	5,000	[1] 30	2,500
Entity Registration Update	250	1	250	[1] 15	62
Authorized Agent Designation	100	1	100	[1] 10	16
Authorized Agent Designation Update	5	1	5	[1] 5	0.42
61.15, Disputed Reports/ Secretarial Review:					
Initial Request	750	1	750	[1] 10	125
Request for Secretarial Review	37	1	37	[1] 480	296
Total	76,177	.....	1,278,654	.....	186,808

[1] Minutes.

Other forms used in the management of the HIPDB include the following: