sample through the end of their first grade year of school.

FACES currently involves five phases of data collection. The first phase was a Spring, 1997 field test in which approximately 2400 parents and children were studied in a nationally stratified random sample of 40 Head Start programs. The second and third phases occurred in Fall, 1997 (Wave 1) and Spring, 1998 (Wave 2) when data were collected on a sample of 3200 children and families in the same 40 programs. The Spring, 1998 data collection included assessments of both Head Start children completing the program and former Head Start children completing kindergarten (kindergarten field test), as well as interviews with their parents and ratings by their kindergarten teachers. In the fourth and fifth phases, follow-up continued for a second program year, plus a kindergarten follow-up. The current plan is to extend data collection in Spring of the first-grade year for both cohorts of children, those completing kindergarten in Spring, 1999, and those completing kindergarten in Spring, 2000.

This schedule of data collection is necessitated by the mandates of the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103–62), which requires that the Head Start Bureau move expeditiously toward development and testing of Head Start Performance Measures, and by the 1994 reauthorization of Head Start (Head Start Act, as amended, May 18, 1994, Section 649(d)), which requires assessment of Head Start's quality and effectiveness. These mandates were reinforced by the Head Start Act Reauthorization of October, 1998, which called for planning for a study of Head Start children to continue follow-up through first grade.

Respondents: Individuals or Households.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Year 2000—First grade parents	1987	1	.5	994
Year 2000—First grade children	1987	1	.67	1331
Year 2000—First grade teachers	1987	1	.33	656
Year 2001—First grade parents	1168	1	.5	584
Year 2001—First grade children	1168	1	.67	783
Year 2001—First grade teachers	1168	1	.33	385
Estimated Average Annual Burden Hours				2,367

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 17, 1999.

Bob Driscoll,

Acting Reports Clearance Officer.

[FR Doc. 99–33291 Filed 12–23–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Subcommittee of the Biological Response Modifiers 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: Subcommittee of the Biological Response Modifiers 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 13, 2000, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Xenotransplantation Subcommittee will discuss the following public health issues concerning xenotransplantation: (1) Update of scientific data concerning porcine endogenous retrovirus, (2) blood donor deferral, and (3) examination of risks posed by different types of xenotransplantation products.

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 3, 2000. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:45 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 3, 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 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