TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
211.80(d)	4,184	.25	1,046	.1	105
211.100(b)	4,184	3	12,552	2	25,104
211.105(b)	4,184	.25	1,046	.25	262
211.122(c)	4,184	50	209,200	.25	52,300
211.130(e)	4,184	50	209,200	.25	52,300
211.132(c)	1,698	20	33,960	.5	16,980
211.132(d)	1,698	.2	340	.5	170
211.137	4,184	5	20,920	.5	10,460
211.160(a)	4,184	2	8,368	1	8,368
211.165(e)	4,184	1	4,184	1	4,184
211.166(c)	4,184	2	8,368	.5	4,184
211.173	1,077	1	1,077	.25	269
211.180(e)	4,184	.2	837	.25	209
211.180(f)	4,184	.2	837	1	837
211.182	4,184	2	8,368	.25	2,092
211.184	4,184	3	12,552	.5	6,276
211.186	4,184	10	41,840	2	83,680
211.188	4,184	25	104,600	2	209,200
211.192	4,184	2	8,368	1	8,368
211.194	4,184	25	104,600	.5	52,300
211.196	4,184	25	104,600	.25	26,150
211.198	4,184	5	20,920	1	20,920
211.204	4,184	10	41,840	.5	20,920
Total					848,625

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22435 Filed 9–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0077]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by October 24, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0291.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

MedWatch: Food and Drug Administration Medical Products Reporting Program (OMB Control Number 0910–0291)—Extension

Under sections 505, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act); (21 U.S.C. 355, 360b, 360c, 360e, and 393); and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act, a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling.

Under section 4 of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) (21 U.S.C. 341), section 402 of the act (21 U.S.C 342) is amended so that FDA must bear the burden of proof to show a dietary supplement is unsafe.

To carry out its responsibilities, the agency needs to be informed whenever an adverse event, product problem or error with use of a medication or device occurs. Only if FDA is provided with such information will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce or eliminate the public's exposure to the risk through regulatory action. To ensure the marketing of safe and effective products, certain adverse events must be reported. Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR parts 310, 314, 600, 803, and 1271, specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, 803.56, and 1271.350(a).

Two forms are available from the agency to implement these provisions for reporting of adverse events, product problems, and medication/device use errors for FDA regulated products such as medications, devices, biologics, including human tissue, cell, tissue and cellular-based products, special nutritional products, and cosmetics, as well as any other products that are regulated by FDA. Form FDA 3500 may be used for voluntary (i.e., not mandated by law or regulation) reporting by healthcare professionals and the public. Form FDA 3500A is used for mandatory reporting (i.e., required by law or regulation).

Respondents to this collection of information are healthcare professionals, hospitals and other user facilities (e.g., nursing homes, etc.), consumers, manufacturers of biological, drug, and dietary supplement products or medical devices, and importers.

II. Use of Form FDA 3500 (Voluntary Version)

The voluntary version of the form is used to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required by law or regulation to submit reports to the agency or the manufacturer, with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Those mandatory reports are not submitted to FDA on the 3500 or 3500A form, but are submitted to the joint FDA/Centers for Disease Control and Prevention Vaccines Adverse Event Reporting System (VAERS) on the VAERS–1 form. (See *http://www.vaers.hhs.gov/pdf/vaers_form.pdf*.)

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries. The DSHEA puts the responsibility on FDA to prove that a particular product is unsafe. The agency depends on the voluntary reporting by health professionals and consumers of suspected adverse events associated with the use of dietary supplements.

III. Use of Form FDA 3500A (Mandatory Version)

A. Drug and Biologic Products

In sections 505(j) (21 U.S.C. 355(j)) and 704 (21 U.S.C. 374) of the act, Congress has required that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs), 600 (biologics) and 1271 (Human Cells, Tissues, and Cellular and Tissue-Based Products). Parts 310, 314, and 600 mandate the use of FDA Form 3500A form for reporting to FDA on adverse events that occur with drugs and biologics. The Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462, 120 Stat. 3469) amended the act with respect to adverse event reporting and recordkeeping for dietary supplements and non-prescription drugs marketed without an approved application. The law provides for the mandatory reporting to FDA of serious adverse events for over-the-counter (OTC) drug products. The authority is 21 U.S.C. 379aa-1(a)(3), (b)(1) and/or section 761(a)(3) and (b)(1) of the act.

B. Medical Device Products

Section 519 of the act (21 U.S.C. 360i) requires manufacturers and importers of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may, by regulation, reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness.

The Safe Medical Device Act of 1990, signed into law on November 28, 1990, amends section 519 of the act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 mandates the use of FDA Form 3500A for reporting to FDA on medical devices.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) signed into law October 26, 2002, amended section 519 of the act. The amendment (section 303 of MDUFMA) required FDA to revise the MedWatch forms to facilitate the reporting of information relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.

C. Dietary Supplements

The Dietary Supplement and Nonprescription Drug Consumer Protection Act amended the act with respect to adverse event reporting and

recordkeeping for dietary supplements and non-prescription drugs marketed without an approved application. The law provides for the mandatory reporting to the Food and Drug Administration of serious adverse events for dietary supplements. The authority is 21 U.S.C. 379aa-1(a)(3), (b)(1) and/or section 761(a)(3) and (b)(1) of the act.

IV. Proposed Modifications to Forms

FDA has proposed no modification to either the Form FDA 3500 or Form FDA 3500A at this time. The requested extension for both forms will only result in changes in the form instructions rather than in any content or formatting for either form. The ability to change the instructions will allow for any and all necessary clarifications in the use of the form and can reflect the current range of reportable products (e.g., OTC products and dietary supplements).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER					
Form 3500	23,033	1	23,033	0.6	13,820
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80)	600	765	459,102	1.1	505,012
CDRH					
Form 3500	4,375	1	4,375	0.6	2,625
Form 3500A (Part 803)					
User	1,084	3	3,252	1.1	3,577
Facilities	80	18	1,470	1.1	1,617
Importers	2,946	48	141,405	1.1	155,545
Manufacturers					160,739
Total 3500A					163,364
Total CDRH					
CFSAN					
Form 3500	479	1	479	0.6	287
Form 3500A	0	0	0	1.1	0
Form 3500					16,732
Form 3500A					665,751
Total					682,483

[1]CBER (Center for Biologics Evaluation and Research), CDER (Center for Drug Evaluation and Research), CDRH (Center for Devices and Radiological Health), and CFSAN (Center for Food Safety and Applied Nutrition). Form FDA 3500 is for voluntary reporting. Form FDA 3500A is for mandatory reporting. There are no capital costs or operating and maintenance costs associated with this collection of information. (NOTE—The figures shown in table 1 of this document are based on actual calendar year 2007 reports and respondents. There is no burden calculation for the mandatory reporting requirements which went into effect on December 22, 2007, for dietary supplements (CFSAN) or OTC drugs (CDER). These estimates and opportunities for public comment will be addressed separately by FDA and will also be incorporated in subsequent requests for extension of Forms FDA 3500 and 3500A.)

In the **Federal Register** of February 15, 2008 (73 FR 8879), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received three comments. There were no comments submitted concerning the Form FDA 3500, voluntary reporting form. All comments addressed Form FDA 3500A, the mandatory reporting form. There were no comments submitted concerning the mandatory 3500A form that addressed questions of whether the information obtained is necessary for the proper performance of FDA's functions or comments about the practical utility of this information. There was one comment about the accuracy of the burden estimate for a subset of reports (dietary supplements). The remainder of the comments were specific suggestions for modifications of either the content or format of various fields to enhance clarity of information. There was also one comment about the use of information technology to support collection.

One comment noted that there was no burden estimate offered for the mandatory reports that would be expected for serious adverse events associated with dietary supplement products. In addition, the comment offered an estimate of 30 minutes to 1 hour for the time to complete, route for approval, and submit a mandatory report for a dietary supplement product. FDA agrees with this estimate and, for mandatory reports, has used a 1.1 hour estimate for time to complete a report. FDA has chosen to not attempt to estimate a reporting burden for mandatory dietary supplement report volume, because the burden estimate used in this request for extension of both reporting forms is based on actual reports for the calendar year 2007 and there was no requirement for submission of mandatory dietary supplement reports until December 22, 2007. To address PRA burden estimates for mandatory reporting required for both dietary supplements and OTC products under the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006, FDA will submit this burden estimate information under a separate **Federal Register** notice process.

There were several comments suggesting a variety of changes in the formatting of certain fields in the mandatory form, changes to existing text, or addition of extra text. These changes were suggested to ''reduce confusion and capture additional clarifying information.'' For example, it was suggested that more space be allotted to certain fields to accept more

text or that certain text fields be modified to ask supplemental questions of the reporter.

FDA has carefully considered each of these changes but does not concur with making these elective changes, which are not based on any changes in law, rule, or regulation. Because FDA encourages electronic submission of postmarketing adverse event reports by mandatory reporters, and the majority of mandatory reporters use the paper-based Form FDA 3500A only for backup purposes, the agency believes that it would be an unfair burden to manufacturers who submit electronically to expend resources to change their electronic versions of the paper document which would be used only in times of rare network or server outages. FDA believes that each of these suggested elective text changes and additions can be addressed satisfactorily with specific clarifying information provided in the instructions section that supplements Form FDA 3500A.

One comment suggests that FDA modify the forms to include wording as a ''disclaimer by consumer authorizing the treating physician to speak with a manufacturer's representative.'' FDA disagrees with the inclusion of this type of information within the standard reporting form and believes that this type of information is best treated as part of other documentation maintained by the mandatory reporter.

One comment suggests that provisions be made to allow for the inclusion of attachments with the serious adverse event report. FDA agrees and attachments are currently permitted both as supplements to mailed and faxed submissions. One comment acknowledged and supported the recently announced development of a unified federal approach to adverse event reporting, and suggested that this approach will ease the reporting burden for both industry and FDA and indirectly benefit consumers.

The newly revised Forms FDA 3500 and 3500A with updated instructions, which will address several comments' concerns about clarity, will be made available, upon OMB approval, on the FDA's MedWatch Web site at *http://www.fda.gov/medwatch/getforms.htm*.

Dated: September 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22440 Filed 9–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Endocrinologic and Metabolic 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Endocrinologic and Metabolic 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 October 21, 2008, from 8 a.m. to 5 p.m.

Location: Crowne Plaza Hotel/Washington DC–Silver Spring, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD, 301–589–0800.

Contact Person: Paul Tran, 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, FAX: 301–827–6776, e-mail: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On October 21, 2008, the committee will begin with a closed session from 8 a.m. to 11 a.m. Following the closed session, from 11 a.m. to 5 p.m., the meeting will be open to the public. The committee will discuss the safety and efficacy of biologic license application (BLA) 125291, MYOZYME (alglucosidase alfa), Genzyme Corp., for the treatment of late onset Pompe disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: On October 21, 2008, from 11 a.m. to 5 p.m., the meeting is open to the public. 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 on or before October 7, 2008. Oral presentationsfrom the public will be scheduled between approximately 12 noon and 1 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before September 29, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 30, 2008.

Closed Committee Deliberations: On October 21, 2008, from 8 a.m. to 11 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). During this session, the committee will discuss the manufacturing as well as relevant biochemical and physiochemical attributes of alglucosidase alfa and how they impact clinical efficacy.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee