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

meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: September 16, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–22437 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–0513]

Product Tracing Systems for Fresh Produce; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing two public meetings regarding product tracing systems for fresh produce. The purpose of the meetings is to stimulate and focus a discussion about mechanisms to enhance product tracing systems for fresh produce and to improve FDA's ability to use the information in such systems to identify the source of contamination associated with fresh produce-related outbreaks of foodborne illness. This discussion will help FDA determine what short and long term steps we should take to enhance the current tracing system.

DATES: See ''How to Participate in the Meetings'' in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See ''How to Participate in the Meetings'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: *For registration, requests to make an oral presentation, and submission of written material for the presentation*: Deborah Harris, EDJ Associates, Inc., 11300 Rockville Pike, suite 1001, Rockville, MD 20852, 240–221–4326, FAX: 301–945–4295, e-mail: *dharris@edjassociates.com*.

For general questions about the meeting, to request onsite parking for the October 16 meeting, or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–009), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1731, e-mail: *Juanita.Yates@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. How to Participate in the Meetings

Stakeholders will have an opportunity to provide oral comments. Due to limited space and time, we encourage all persons who wish to attend one or both of the meetings, including those requesting an opportunity to make an oral presentation at one or both of the meetings, to register in advance. Depending on the number of oral presentations, we may need to limit the time of each oral presentation (e.g., 5 minutes each). If time permits FDA may grant requests for an opportunity to make a presentation from individuals or organizations that did not register in advance.

Table 1 of this document provides information on participation in the meetings and on submitting comments.

TABLE 1.

	Date	Address	Electronic Address	Other Information
First Public Meeting	October 16, 2008, from 9 a.m. to 5 p.m.	Harvey W. Wiley Federal Building, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740-3835 (Metro stop: College Park on the Green Line)		
Advance registration	October 8, 2008	We encourage you to use electronic registration if possible.[1]	*http://www.cfsan.fda.gov/register.html*	Registration information, information on requests to make an oral presentation, and written material associated with an oral presentation may be posted without change to *http://www.regulations.gov*, including any personal information provided.
Make a request for oral presentation	October 1, 2008			
Provide a brief description of the oral presentation and any written material for the presentation	October 8, 2008			
Request special accommodations due to a disability	October 8, 2008	See **FOR FURTHER INFORMATION CONTACT**		
Request onsite parking	October 10, 2008	See **FOR FURTHER INFORMATION CONTACT**		