melamine-related compounds below 2.5 ppm do not raise public health concerns. This interim safety/risk assessment was developed rapidly due to the extremely time-sensitive need to understand the nature of the potential risk. We are seeking public comment on this interim safety/risk assessment. In addition, it will undergo expert peer review.

II. Safety/Risk Assessment

A human health safety/risk assessment is a scientifically-based methodology used to estimate risk to human health from exposure to specific compounds such as contaminant(s) in food. The interim safety/risk assessment of melamine and its analogues builds upon the 2007 Melamine Safety/Risk Assessment and considers the toxicological profile of melamine and its analogues, including the observed results from controlled animal studies conducted with melamine.

For infant formula, there are gaps in our scientific knowledge about the toxicity of melamine and its analogues in infants, including:

1. The consequences of the continuous use of infant formulas as the sole source of nutrition;

2. The uncertainties associated with the possible presence and co-ingestion of more than one melamine analogue; and

3. For premature infants with immature kidney function, the possibility that they may be fed these formulas as the sole source of nutrition and thus on a body weight basis experience greater levels of intake for a longer time than is experienced by term infants. For these reasons, there is too much uncertainty for FDA to establish a level of melamine and its analogues in infant formula that does not raise public health concerns. However, it is important to understand that this does not mean that any exposure to any detectable level of melamine and melamine-related compounds in formula will result in harm to infants.

In food products other than infant formula, to estimate the level of melamine that does not raise public health concerns, FDA used a worst case exposure scenario in which one-half of a person's total daily dietary intake (Tolerable Daily Intake (TDI), an estimate of the maximum amount of an agent to which an individual could be exposed on a daily basis over the course of a lifetime without appreciable health risk) is contaminated with melamine and its analogues. The TDI used, 0.63 milligrams/kilogram (mg/kg) body weight/day (bw/d), was developed in 2007 in collaboration with the Food Safety and Inspection Service of the Department of Agriculture and in consultation with the Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Department of Homeland Security.[1] In the present interim safety/risk assessment, we estimated that if 50 percent of the diet were contaminated at a level of 2.5 ppm of melamine and its analogues, a person's daily intake would equal 0.063 mg/kg bw/d —a level 10-fold below the TDI. Therefore, FDA concludes that levels of melamine and melamine-related compounds below 2.5 ppm do not raise public health concerns in food other than infant formula.

Recognizing the time-sensitive need for the safety/risk assessment, FDA invites comments concerning:

1. The assessment approach used;

2. The assumptions made;

3. The data used; and

4. The transparency and clarity of the report.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

The interim safety/risk assessment is available electronically at *http://www.cfsan.fda.gov/~dms/melamra3.html*.

Dated: November 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26869 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

[1]Interim Melamine and Analogues Safety/Risk Assessment, May 25, 2007 (*http://www.cfsan.fda.gov/~dms/melamra.html*).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices 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: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices 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 December 5, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Neel J. Patel, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., 240–276–3700, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512624. 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: The committee will discuss, make recommendations and vote on a premarket approval application, sponsored by Emphasys Medical, Inc., for the Emphasys Zephyr Endobronchial Valve System, which is intended to improve forced expiratory volume in the first second (FEV1) and 6-minute walk test distance in patients with severe heterogeneous emphysema who have received optimal medical management. 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: 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 November 26, 2008. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of the committee deliberations and for approximately 30 minutes near the end of committee deliberations. 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 November 20, 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 November 24, 2008.

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 AnnMarie Williams, Conference Management Staff, at 240–276–8932, 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: November 5, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–26965 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0581]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representative on Public Advisory Committees and Request for Nominations for Nonvoting Industry Representative on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its public advisory committees for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CBER's public advisory committees. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating the interest to FDA by December 15, 2008, for vacancies listed in the notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by December 15, 2008.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Gail Dapolito (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Gail Dapolito, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20892, 301–827–1289, *gail.dapolito@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The agency requests nominations for nonvoting industry representatives to the following advisory committees.

I. CBER Advisory Committees

A. The Cellular, Tissue and Gene Therapies Advisory Committee

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner).

B. Vaccines and Related Biological Products Advisory Committee

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which FDA has regulatory responsibility. The Committee as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner.

C. Transmissible Spongiform Encephalopathies Advisory Committee

The Committee reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health as determined by the Commissioner. The Committee will make recommendations to the Commissioner regarding the regulation of such products.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a