about the product, a description of the details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the agency.

As stated earlier, the guidance provides information on how the agency will interpret and apply section 119(a) of the Modernization Act, specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82). The information collection provisions in § 312.47 concerning End-of-Phase 2 meetings and Pre-NDA meetings have been approved by OMB (OMB Control No. 0910–0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting these additional estimates for OMB approval.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Meeting Requests and Information Packages	No. of Respondents	No. of responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Meeting Requests					
CDER	907	2.44	2,210	10	22,100
CBER	144	1.99	287	10	2,870
Total					24,970
Information Packages					
CDER	774	2.20	1,705	18	30,690
CBER	120	1.65	198	18	3,564
Total					34,254
Grand Total					59,224

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

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*.

Dated: November 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27008 Filed 11–12–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0574]

Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans.'' The interim safety/risk assessment evaluated exposure to melamine and its analogues (cyanuric acid, ammelide and ammeline) in infant formula and other foods to identify, where possible, a level of exposure that would not raise public health concerns. FDA is seeking public comment on the interim safety/risk assessment.

DATES: Comments on the interim safety/risk assessment must be submitted by January 12, 2009.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1057, FAX: 301–436–2973, or e-mail: *Annette.McCarthy@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the interim safety/risk assessment is to identify the level of melamine and melamine-related compounds in food which would not raise public health concerns. On September 11, 2008, FDA learned that melamine may be contained in an infant formula manufactured by a firm in China. As of September 21, 2008, FDA learned that a total of 52,857 cases of nephrolithiasis (and, in some instances, renal failure) had been reported in China linked to consumption of this contaminated powdered formula. There have been approximately 13,000 hospitalizations, and at least 3 deaths have been confirmed to date. The results of an investigation conducted in China indicated that Chinese-produced powdered infant formula was linked to these illnesses; no cases were associated with liquid infant formula. Test results conducted in China on samples of the powdered infant formula showed that they contained a wide range of concentrations (0.1 parts per million (ppm) to greater than 2,500 ppm melamine). In addition, other countries have reported detection of melamine in other product categories, such as confections and beverages.

The interim safety/risk assessment concludes that, based on currently available data and information, 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. In foods other than infant formula, FDA concludes that levels of melamine and

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]

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[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.