

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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.

Notice of Participation—(OMB Control Number 0910-0191)—Extension

Section 12.45 (21 CFR 12.45), issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires

that any person filing a notice of participation, state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e), the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected

information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the pre-hearing conference and commits participation.

The respondents are individuals or households, State or local governments, not-for-profit institutions and businesses, or other for-profit groups and institutions.

In the **Federal Register** of December 29, 2008 (73 FR 79495), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| Section 502 of the FFD&C Act/ Section 351 of the PHS Act | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 12.45 | 8 | 1 | 8 | 3 | 24 |

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

The burden estimates for this collection of information are based on agency records and experience over the past 3 years.

Dated: March 30, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0166]

Economically Motivated Adulteration; Public Meeting; Request for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting pertaining to economically motivated adulteration (EMA). The purpose of the meeting is to stimulate and focus a discussion about ways in which the food (including dietary supplements and animal food), drug, medical device, and cosmetic industries, regulatory agencies, and other parties can better predict and prevent economically motivated adulteration with a focus on situations that pose the greatest public health risk. FDA invites interested individuals,

organizations, and other stakeholders, including industry representatives, to present information pertaining to predicting and preventing EMA of food (including dietary supplements and animal food), drugs, medical devices, and cosmetics. The agency also requests interested parties to submit comments on this issue to the public docket.

DATES: The public meeting will be held on May 1, 2009, from 9 a.m. to 5 p.m. Submit written or electronic comments by August 1, 2009. See section I of the **SUPPLEMENTARY INFORMATION** section for deadlines regarding the meeting.

ADDRESSES: The public meeting will be held in the Wiley Auditorium, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740-3835. 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 the docket at <http://www.regulations.gov>. See section V of this document for additional information on submitting comments.

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 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 Meeting

Due to limited space and time, we encourage all persons who wish to attend the meeting, including those requesting an opportunity to make an oral presentation at the meeting, to register in advance. Attendees may register in advance for the meeting by April 23, 2009. Requests for oral presentations should be made by April 16, 2009. Presenters should submit final presentations by April 23, 2009, in order for us to accommodate their request. Requests for special accommodations due to disability should be made by April 23, 2009. Requests for onsite parking may be made until April 27, 2009.

We encourage attendees to register for this meeting electronically at <http://www.fda.gov/oc/meetings/ema.html>. You may also register by mail, fax, e-mail, or telephone by providing registration information (including name, title, firm name, address, telephone number, fax number, and e-mail address) to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Attendees will have an opportunity to provide oral comments. Depending on the number of oral presentations, we

may need to limit the time of each oral presentation (e.g., 5 minutes each). Requests to make an oral presentation, submission of written material for the presentation, requests for special accommodations due to disability, and requests for onsite parking should be directed to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

II. Background on the Meeting

A. Suspected Economically Motivated Adulteration of FDA-Regulated Products

For purposes of this public meeting, FDA proposes a working definition of EMA as the fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain. EMA includes dilution of products with increased quantities of an already-present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution.

Several recent incidents involving FDA-regulated products are suspected to be examples of EMA. These incidents illustrate the potential for serious public health harm from such adulterated products.

In March 2007, FDA received reports of kidney failure among cats and dogs and a report that cats died during taste tests of certain brands of pet food. In the subsequent investigation, melamine and melamine-related compounds were found in products labeled as wheat gluten and rice protein concentrate that had been imported from China. Wheat gluten and rice protein concentrate are common ingredients in numerous pet food products sold in the United States. Melamine and its related compounds are not approved for use as an ingredient in animal or human food, and FDA believes it was these contaminants that made the cats and dogs sick. At certain exposure levels, the interaction of melamine and melamine-related compounds appears to cause the formation of crystals in the kidneys, resulting in kidney damage. Based on the information that FDA has, it appears that these contaminants were added to the products handled by Chinese suppliers to increase the apparent protein content in those products. Consumers and veterinarians have since reported many more animal illnesses and deaths potentially

associated with pet foods made from these products. Over 150 brands of pet food and 1,000 products were voluntarily recalled by a number of companies.

In January 2008, FDA received reports of adverse reactions in pediatric dialysis patients in the U.S. Initial investigations by the Centers for Disease Control and Prevention indicated that the adverse events appeared to be associated with heparin manufactured by Baxter Healthcare Corp. that was administered during the dialysis procedures. In January and February 2008, Baxter Healthcare Corp. voluntarily recalled all of its heparin products. FDA's investigation ultimately identified almost 150 U.S. deaths occurring between January 1, 2007, and May 31, 2008, that appeared to be associated with the use of these heparin products. During the investigation, FDA scientists collaborated with academia and industry and identified a contaminant in the heparin active pharmaceutical ingredient (API) obtained from suppliers in China. The contaminant was a heparin-like molecule whose presence in heparin API was not detected by the United States Pharmacopoeia (USP) release tests for heparin. The contaminant was identified as oversulfated chondroitin sulfate (OSCS). FDA posted two new analytical tests to detect the contaminant OSCS on its Web site in March 2008, and the agency collaborated with USP to revise the test methods and modify the monograph for heparin to test for OSCS. These new tests were used on heparin API imported into the United States and throughout the world. Contaminated heparin API has been found in 11 countries.

In September 2008, FDA issued a Health Information Advisory in response to reports of melamine contaminated milk-based infant formula manufactured in China. Melamine was apparently added to diluted milk in order to increase measured nitrogen levels (indicators of protein content) and thereby inflate the apparent protein content found in the product. FDA issued further advisories to address additional milk-based products. To date, official reports from the Chinese Ministry of Health state that nearly 300,000 Chinese infants were sickened by the contaminated infant formula, and that six infant deaths were likely due to the contamination. There have been no confirmed illnesses or deaths in the United States attributed to melamine in products containing milk or milk-derived ingredients, although some contaminated products were found at

ethnic markets selling imported products.

Adulteration of glycerin, an ingredient in cough syrup and other drugs, with diethylene glycol (DEG) has resulted in several mass poisonings around the world in the past two decades. In 1996, contaminated acetaminophen syrup was responsible for the deaths of more than 70 children in Haiti. In 2006, tainted cough syrup resulted in dozens of deaths in Panama. In Nigeria, between 2008 and 2009, more than 50 children died after ingesting contaminated teething syrup. Incidents of DEG contamination in these two decades have not resulted in any reported U.S. deaths or illnesses, but in 2007, foreign-made toothpaste contaminated with DEG was reported in the United States resulting in recalls and restriction on imports of suspect toothpastes. FDA has collaborated with USP to revise the test methods for glycerin and other monographs to test for the presence of DEG.

As the preceding examples illustrate, despite longstanding FDA requirements to assure the safety of regulated products, such as requirements for the use of ingredients of known identity and quality in drugs, economically motivated adulteration remains a public health threat.

B. FDA Science Board Meeting and EMA Workgroup

At the October 31, 2008, meeting of the FDA Science Board, FDA presented a conceptual model of EMA. The model describes circumstances and factors that are likely to lead to EMA, and points to certain types of information that may be useful in trying to prevent EMA. In response to the feedback obtained during the Science Board Meeting, FDA formed an internal working group focused on predicting and addressing EMA ("EMA Workgroup"). At the February 25, 2009, meeting of the Science Board, FDA announced its intent to hold a public meeting on EMA.

III. Purpose of Meeting and Questions for Discussion

The purpose of the public meeting is to raise awareness about the potential for EMA and solicit input and comments on how industry, regulators, and other parties can better predict, prevent, and address EMA. FDA's EMA Workgroup has developed a set of questions to focus discussion on the matter. These questions apply to food (including dietary supplements and animal food), drug, device and cosmetic products and their components/ingredients. The EMA Workgroup requests comment and input on these

questions, as well as any responses to the questions themselves based on information that may already be in the public domain. The EMA Workgroup further requests comment on the utility of the working definition of EMA used here. A transcript of the public meeting will be made available.

Please note that FDA does not wish to publicize sensitive information that could potentially be used by those who wish to commit EMA or other adulteration or that identifies those who may be committing adulteration FDA would like to remind the public that if they have information about these or any other problems they have encountered with FDA products, they may report such information at <http://www.fda.gov/opacom/backgrounders/problem.html>. In addition, if the public has information pertaining to suspected criminal activity with regard to FDA-regulated products (e.g., information about individuals who may be committing EMA or other adulteration), they may contact FDA's Office of Criminal Investigations at <http://www.fda.gov/oci/default.htm> in lieu of responding publicly to this document.

(1) General Questions:

- a. What information should U.S. regulators seek and from what sources to help predict and prevent EMA? What further steps can U.S. regulators take to predict and prevent EMA?
- b. What are members of industry doing to prevent EMA? What further steps can industry take to prevent EMA?
- c. What recent examples of known or suspected EMA domestically and internationally should U.S. regulators study and learn from?
- d. What information do other organizations (including, but not limited to, trade organizations and security service providers) have that would be useful in predicting and preventing EMA? What are members of other organizations doing to prevent EMA?
- e. What are other government regulators within and outside of the United States doing to predict and address EMA?
- f. What indicators (economic-based, chemistry-based, etc.) might be used to detect potential EMA?

(2) Questions pertaining to attributes of products, components/ingredients that may be at risk for EMA:

- a. What are attributes of products or components/ingredients of products that may cause them to be more vulnerable to EMA?
- b. What food products are marketed based on measured content of

certain constituents, such as content of certain proteins, certain fats, or certain sugars?

- (3) Questions pertaining to changes in the marketing environment: What changes relevant to the risk for EMA have occurred recently in:
 - a. The marketing environment of products or components/ingredients?
 - b. The sourcing and/or distribution of products?
 - c. The prices, output, imports or exports of products or components/ingredients?
 - d. The supply of components/ingredients or source materials for products?
- (4) Questions about detection methods:
 - a. What analytical equipment or methods currently used by industry and regulators to establish the identity or quality of a product or its conformity to specifications may be inadequate to detect evidence of EMA or adulterated products or ingredients?
 - b. Are there appropriate analytical methods/equipment that could be used instead of, or in addition to, existing methods or equipment in particular situations?
 - c. What rapid methods can be used to detect adulteration of products or ingredients?
- (5) What systems are currently being used to track and verify components/ingredients from their source?
- (6) Are there particular types of industry structures or supply chains that are especially vulnerable to or secure from potential EMA?

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

V. 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.

Dated: April 1, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases Diabetes Mellitus Interagency Coordinating Committee; Notice of Meeting

The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on May 6, 2009, from 12:30 to 4:30 p.m. at Building 31C, Conference Room 6C, on the NIH campus, 9000 Wisconsin Ave., Bethesda, MD. The meeting will be open to the public, with attendance limited to space available. Non-federal individuals planning to attend the meeting should notify the Contact Person listed on this notice at least 2 days prior to the meeting. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below at least 10 days in advance of the meeting.

The DMICC facilitates cooperation, communication, and collaboration on diabetes among government entities. DMICC meetings, held several times a year, provide an opportunity for members to learn about and discuss current and future diabetes programs in DMICC member organizations and to identify opportunities for collaboration. The May 6, 2009, DMICC meeting will discuss "Federally Supported Diabetes-Related National Education Programs."

Any member of the public interested in presenting oral comments to the Committee should notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present