

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Intermediary survey .....	60	1	.5	30

**Estimated Total Annual Burden Hours:**

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447. Attn: ACF Reports Clearance Office. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 4, 2006.

**Robert Sargis,**

*Reports Clearance Officer.*

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BILLING CODE 4184-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Detroit District,

in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

**Date and Time:** The public workshop is scheduled for Wednesday, November 15, 2006, from 8:30 a.m. to 5 p.m. and Thursday, November 16, 2006, from 8:30 a.m. to 4:30 p.m.

**Location:** The public workshop will be held at the Sheraton Indianapolis Hotel & Suites, 8787 Keystone Crossing, Indianapolis, IN 46240, 317-846-2700, FAX: 317-574-6775.

**Contact:** Nancy Bellamy, Food and Drug Administration, 300 River Pl., suite 5900, Detroit, MI, 48207, 313-393-8143, FAX: 313-393-8139, e-mail: [nancy.bellamy@fda.hhs.gov](mailto:nancy.bellamy@fda.hhs.gov).

**Registration:** Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of \$575 (member), \$650 (nonmember), or \$525 (Government employee nonmember). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA, 18914. To register via the Internet go to [http://www.socra.org/html/FDA\\_Conference.htm](http://www.socra.org/html/FDA_Conference.htm) (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800-SoCRA92 (800-762-7292), or 215-822-8644, or via e-mail: [socramail@aol.com](mailto:socramail@aol.com). Attendees are responsible for their own accommodations. To make reservations at the Sheraton Indianapolis Hotel & Suites, at the reduced conference rate, contact the Sheraton Indianapolis Hotel

& Suites (see *Location*) before October 22, 2006. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact Nancy Bellamy (see *Contact*) at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The workshop on FDA clinical trials statutory and regulatory requirements helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA regulation of the conduct of clinical research; (2) medical device, drug, biological product and food aspects of clinical research; (3) investigator initiated research; (4) pre-investigational new drug application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresearch inspections; and (11) what happens after the FDA inspection. FDA has made education of the research community a high priority to ensure the quality of clinical data and protect research subjects. The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed to small businesses.

Dated: August 4, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0107]

#### Food and Drug Administration-Regulated Products Containing Nanotechnology Materials; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) will hold a public meeting October 10, 2006, on FDA-regulated products containing nanotechnology materials, and has opened a docket on FDA-regulated products containing nanotechnology materials. The purpose of the meeting will be to help FDA further its understanding of developments in nanotechnology materials that pertain to FDA-regulated products. FDA is interested in learning about the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices, whether there are new or emerging scientific issues that should be brought to FDA's attention, and any other scientific issues about which the regulated industry, academia, and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

**DATES AND TIMES:** The public meeting will be held October 10, 2006, from 9 a.m. to 5 p.m.

**REGISTRATION:** You may register at <http://www.fda.gov/nanotechnology/>. We will also post the agenda at <http://www.fda.gov/nanotechnology/> prior to the meeting.

**ADDRESSES:** The public workshop will be held at the Natcher Auditorium, National Institutes of Health Campus, 9000 Rockville Pike, bldg. 45, Bethesda, MD. We will also post the address for the meeting at <http://www.fda.gov/nanotechnology/>.

Written or electronic comments may be submitted by November 10, 2006. 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.fda.gov/dockets/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Poppy Kendall, Food and Drug Administration (HF-11), 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: [poppy.kendall@fda.hhs.gov](mailto:poppy.kendall@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Why Are We Holding a Public Meeting?

Nanotechnology is defined in a variety of ways. The National Nanotechnology Initiative (a U.S. Government research and development coordinating program) refers to nanotechnology as "the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications" (<http://www.nano.gov>). A nanometer is a billionth of a meter, and is approximately the width of 10 hydrogen atoms lined up side by side. (A human hair is about 80,000 nanometers in width. Deoxyribonucleic acid (DNA) is about 2.5 nanometers in width.)

Due to their small size and extremely high ratio of surface area to volume, nanotechnology materials often have chemical or physical properties that are different from those of their larger counterparts. Such differences include altered magnetic properties, altered electrical or optical activity, increased structural integrity, and increased chemical and biological activity. Because of these properties, nanotechnology materials have great potential for use in a vast array of products. Also because of some of their special properties, they may pose different safety issues than their larger counterparts. Of particular interest to FDA, nanotechnology materials may enable new developments in implants and prosthetics, drug delivery, and food processing, and may already be in use in some cosmetics and sunscreens. As part of its critical path initiative, FDA is interested in learning if there are opportunities for it to help overcome scientific hurdles that may be inhibiting the use of nanotechnology in medical product development.

We will be holding this meeting because we are interested in learning about the kinds of new nanotechnology material products under development in

the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices, whether there are new or emerging scientific issues that should be brought to FDA's attention, including issues related to the safety of nanotechnology materials, and any other issues about which the regulated industry, academia, and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

The public meeting will be chaired by the FDA Nanotechnology Task Force. Acting FDA Commissioner Andrew von Eschenbach created this internal task force to help the agency evaluate the increasing use of nanotechnology materials in FDA-regulated products.

For more information about FDA's role regarding nanotechnology products, see our Web page at <http://www.fda.gov/nanotechnology/>.

##### II. How Can You Participate?

You can participate through oral presentation at the meeting or through written or electronic material submitted to the docket. In response to the first notice of this meeting (71 FR 19523, April 14, 2006) we received a large number of responses indicating interest in attending and presenting, and the responses indicated interest in a variety of topics. Therefore, in order to provide the most value to those attending who may be interested in a particular topic, we are likely to divide the meeting into topic areas (for separate, concurrent sessions on those topics) and one general session. Participants would be asked to express a preference for either one of the concurrent sessions or the general session in which to make a presentation. Time allotted for each presentation will depend on the presentation requests received for that session. Furthermore, given the number of responses received, it is likely that it will be necessary to limit presentations to one per individual/organization.

In addition to a session that has a more general focus, we are considering the following three breakout sessions: (1) Topically-administered drugs, biologics, devices and cosmetics; (2) other drugs, biologics and devices; (3) foods (including dietary supplements) and food and color additives, and animal feeds.

We ask that you register early (see **REGISTRATION**) if you intend to provide an oral presentation. The information provided during registration will help us determine further how to organize the day. The final agenda will depend