based survey which will be conduced over one year.

Respondents and Burden Estimates for the Training Ph.D.S Survey

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response (in hours)	Total burden hours
Faculty Survey Instrument	Faculty who advise a PhD candidate.	4,620	1	20/60	1,540

Mary Oliver-Anderson,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E7–24055 Filed 12–11–07; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–115]

Notice of Public Meeting and Availability for Public Comment

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting and availability for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting and request for public comment on the draft Current Intelligence Bulletin (CIB) entitled "Interim Guidance on Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles." The document and instructions for submitting comments can be found at *http://www.cdc.gov/niosh/review/public/115/*. Comments may be provided to the NIOSH docket, as well as given orally at the following meeting.

Public Comment Period: December 14, 2007 through February 15, 2008.

Public Meeting Time and Date: 9 a.m.–4 p.m., January 30, 2008.

Place: Robert A. Taft Laboratories, Taft Auditorium, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Purpose of Meeting: To discuss and obtain comments on the draft CIB "Interim Guidance on Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles." Special emphasis will be placed on discussion of the following:

(1) Do the data support the conclusions of the document?

(2) Are the conclusions appropriate in light of the current understanding of toxicological data?

(3) Is medical surveillance appropriate at this time for workers with potential exposure to engineered nanoparticles; if so, what form(s) of medical surveillance are specific for such workers?

(4) What are the potential benefits, adverse impacts, and limitations of medical screening of workers potentially exposed to engineered nanoparticles?

(5) What are the potential benefits, adverse impacts, and limitations of establishing an exposure registry for workers exposed to engineered nanoparticles?

Status: The forum will include scientists and representatives from various government agencies, industry, labor, and other stakeholders, and is open to the public, limited only by the space available. The meeting room accommodates 80 people. Due to limited space and security clearance requirements, notification of intent to attend the meeting must be made to the NIOSH Docket Office no later than Friday, January 18, 2008. Persons wanting to provide oral comments at the meeting are requested to notify the NIOSH Docket Office no later than January 11, 2008 at 513/533–8611 or by e-mail at *nioshdocket@cdc.gov*. Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come basis. Unreserved walk-in attendees will not be admitted due to security clearance requirements.

Persons wanting to provide oral comments will be permitted up to 20 minutes. If additional time becomes available, presenters will be notified. Oral comments given at the meeting will be recorded and included in the docket. Written comments will also be accepted at the meeting. Written comments may also be submitted to the NIOSH Docket Office, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS C–34, Cincinnati, Ohio 45226, telephone 513/533–8611. All material submitted to the Agency should reference docket number NIOSH–115 and must be submitted by February 15, 2008 (public review closing date) to be considered by the Agency. All electronic comments should be formatted as Microsoft Word. Please make reference to docket number NIOSH–115.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Background: Concerns have been raised about whether workers exposed to engineered nanoparticles will be at increased risk of adverse health effects and whether medical screening or some other type of occupational health surveillance is appropriate for these workers. Although increasing evidence indicates that exposure to some engineered nanoparticles can cause adverse health effects in laboratory animals, insufficient medical evidence exists to recommend the medical screening of workers potentially exposed to engineered nanoparticles. However, NIOSH will continue to assess the scientific evidence and periodically update the guidance on medical screening. Because occupational exposure to engineered nanoparticles is likely to become more common in the future, NIOSH has recommended that employers identify the presence of engineered nanoparticles in their workplace and implement effective efforts to minimize worker exposure to these materials [NIOSH 2006]. This guidance document does not have the force and effect of the law.

Contact Persons for Technical Information: Dr. Paul A. Schulte, M/S C–14, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–8302, or Ralph Zumwalde, M/S C–32, Robert A. Taft Laboratories, 4676 Columbia

Parkway, Cincinnati, Ohio 45226, telephone 513/533–8320.

Reference:

NIOSH [2006]. Approaches to safe nanotechnology: an information exchange with NIOSH. Cincinnati, OH: Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, July 2006. Web address for this document: *http://www.cdc.gov/niosh/topics/nanotech/safenano/*.

Dated: December 5, 2007.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–24047 Filed 12–11–07; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0472]

Agency Emergency Processing Under the Office of Management and Budget Review; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the certification to accompany human drug, biological product, and device applications or submissions.

DATES: Fax written comments on the collection of information by December 17, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title, "Certification to Accompany Drug, Biological Product, and Device Applications or Submissions." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 301–827–4659.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). The emergency processing was requested in order to comply with the provisions of Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), which require this certification to be submitted to FDA beginning no later than December 26, 2007. This information will be needed immediately to implement these provisions of FDAAA, and it is essential to the agency's mission of protecting and promoting the public health. Since the statutory deadline for collecting the information is December 26, 2007, the lack of a form would result in confusion for the sponsors/applicants as the information necessary for FDA to carry out its future statutory responsibilities would not be obvious without the form. While some sponsors/applicants may submit information, it most likely would neither be complete nor provided in a systematic fashion so that it can be more easily retrieved.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Certification to Accompany Drug, Biological Product, and Device Applications or Submissions

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)), will be submitted in the form of a certification with applications and submissions currently submitted to FDA under part 312 (21 CFR part 312) and 21 CFR part 314 (human drugs) approved under OMB control numbers 0910–0014 (expires May 31, 2009) and 0910–0001 (expires May 31, 2008), respectively, part 312 and 21 CFR part 601 (biological products) approved under OMB control numbers 0910–0014 and 0910–0338 (expires June 30, 2010) and 21 CFR parts 807 and 814 (devices) approved under OMB control numbers 0910–0120 (expires August 31, 2010) and 0910–0231 (expires November 30, 2010), respectively.

Title VIII of FDAAA amended the PHS Act by adding section 402(j) (42 U.S.C. 282(j)). The new provisions require additional information to be submitted to the clinical trials data bank (*ClinicalTrials.gov*) previously established by the National Institutes of Health/National Library of Medicine, including expanded information on clinical trials and information on the results of clinical trials. The provisions include new responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

One new provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 354, 360e, or 360j(m)), or under section 351 of the PHS Act (21 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

The proposed collection of information is necessary to satisfy the above statutory requirement.

The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties.