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) Minneapolis District, in cooperation with the Association of Clinical Research Professionals (ACRP), 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, August 23, 2006, from 8 a.m. to 5 p.m. and Thursday, August 24, 2006, from 8:30 a.m. to 12 noon.

Location: The public workshop will be held at The Northland Inn, 7025 Northland Dr., Brooklyn Park, MN 55428, 800–441–6422 or 763–536–8300, FAX: 763–536–8790.

Contact: Amy C. Johnson, Public Affairs Specialist, Food and Drug Administration, 212 3rd Ave. South Minneapolis, MN 55401, 612–758–7131, FAX: 612–334–4134, e-mail: *amy.johnson@fda.hhs.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $220 (ACRP Minnesota chapter member), $280 (nonmember), or $220 (Government employee). Make registration fee payable to ACRP, and mail to the attention of Paul Below, 441 Timberland Dr., Burnsville, MN 55337. To register via the Internet please go to *http://mnacrp.org/* or contact the ACRP webmaster at *webmaster@mnacrp.org*. (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 Paul Below for ACRP at 441 Timberland Dr., Burnsville, MN 55337, 952–882–4083, FAX: 952–223–1665, e-mail: *webmaster@mnacrp.org*.

Attendees are responsible for their own accommodations. To make reservations at the Northland Inn at a rate of $119.00 plus tax, please contact the Northland Inn (see *Location*).

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 Amy Johnson (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 at the workshop include the following:

1. Medical device and drug aspects of clinical research requirements,
2. Pre-investigational device and pre-investigational drug meetings with FDA,
3. Investigator initiated research,
4. Electronic documentation and data capture,
5. Ethical issues in subject enrollment,
6. Informed consent requirements,
7. Adverse event reporting,
8. FDA regulation of institutional review boards,
9. How FDA conducts bioresearch inspections,
10. FDA Enforcement actions associated with clinical research, and
11. How FDA promotes confidence in clinical research.

FDA has made education of the research community a high priority to ensure the quality of clinical data and protect research subjects. The workshop will also help to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic 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: May 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: 2007 National Survey on Drug Use and Health—(OMB No. 0930–0110)—Revision

The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal Government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

With the exception of the addition of several follow-up questions on methamphetamine use, no changes to the questionnaire are proposed for the 2007 NSDUH. The proposed additional questions (age at first use and frequency of use in the past 12 months) will be asked of respondents who denied use of methamphetamine in the ''core'' NSDUH because they didn't think of it as a prescription drug, but in a later series of questions admit to use (Respondents who report use of methamphetamine in the ''core'' already receive questions on age at first use and frequency of use). The additional burden associated with the new questions will be negligible because only a small subset of the sample will receive them.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2007 will be sufficient to permit prevalence estimates for each