

FDA. However, it is assumed that some effort will need to be expended for keeping such lists current.

The burden estimate for the recordkeeping requirements under section 223 of FDAAA in table 2 of this document reflect other recordkeeping requirements for devices listed with FDA and the requirement to provide these records upon request from FDA. These estimates are based on FDA experience.

Dated: October 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0547]

Clinical Development Programs for Sedation Products; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration's (FDA), Center for Drug Evaluation and Research (CDER) is announcing a scientific workshop to solicit information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups. FDA intends to take into account the information provided from this workshop as we develop FDA guidance on clinical development programs for sedation products. FDA issued a notice in the **Federal Register** of November 29, 2010, inviting an interested party, or parties, to facilitate an evaluation of the critical fundamentals of the science related to sedation products and to plan and conduct one or more public meetings to bring together experts in the field, including from academia, patient organizations, and industry, to discuss these issues. FDA has since determined that it will facilitate the evaluation itself, and as a first step, is announcing this workshop.

Date and Time: The public workshop will be held on May 3, 2012, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

Contact Person: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, (301) 796-3519, email: mary.gross@fda.hhs.gov; or Diana Walker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, (301) 796-4029, email: Diana.Walker@fda.hhs.gov.

Registration to Participate in Scientific Panels: If you wish to participate as part of a scientific panel, please email your request to CDER_Sedation_Workshop@FDA.HHS.gov by December 2, 2011. As part of your request, please describe your area of expertise and interest based on the questions identified below. If selected, a subset of panel representatives may be asked to provide formal presentations and/or participate in panel discussions.

Registration to Attend the Workshop and Requests to Participate in Open Public Hearing: If you wish to attend or testify at the open public hearing, please email your registration to CDER_Sedation_Workshop@FDA.HHS.gov by April 2, 2012. Those without email access may register by contacting one of the persons listed in the Contact Person section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm>.

An open public hearing will be held between 1:30 p.m. to 2:30 p.m. on May 3, 2012, during which speaker testimony will be accepted. We will try to accommodate all persons who wish to testify, however, the duration of each speaker's testimony during this open public hearing may be limited by time constraints.

Comments: Submit either electronic or written comments by July 3, 2012. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

If you need special accommodations due to a disability, contact Mary Gross or Diana Walker (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of November 29, 2010 (75 FR 73104), FDA indicated that it was seeking information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups. In the notice, FDA invited any interested party to take on the role of facilitating an evaluation of these issues and as a first step, plan or hold one or more public meetings to discuss these issues. FDA was going to take into account the information provided by these activities in the development of guidance on clinical development programs for sedation products. FDA has now determined that it will conduct the evaluation itself, and is announcing this workshop to further understand the physiology of sedation and clinical trial design issues related to the development of sedation products.

FDA will explore the following topics during this public workshop:

1. For clinical trials of sedation drug products, which surgical and diagnostic procedures would provide the most relevant efficacy and safety data, while still allowing for a reasonable level of feasibility and efficiency?

2. What patient subgroups, other than pediatric, geriatric, and patients with hepatic or renal impairment, would require specific evaluation in clinical trials involving sedation drug products?

3. What is the most appropriate primary efficacy endpoint to assess in a clinical trial of a sedation drug product?

a. Which measurement scales have been adequately studied and validated for use in assessing the endpoint measure recommended previously.

b. Is there a clinically meaningful effect size that should be considered as a minimal requirement for a determination of efficacy?

c. How do the responses to the previous questions differ, if at all, for the pediatric population, in particular, the youngest of these patients who have no or limited communication skills.

4. What secondary efficacy endpoints might be considered clinically meaningful (e.g., subjective and objective assessments of memory, recall, anxiety, agitation, or delirium) if appropriately studied?

5. How should responses to rapid changes in procedural stimulation be considered in the evaluation of efficacy, e.g., the time of initial incision or negotiating a colonoscope around the splenic or hepatic flexure.

6. How do the responses for each of the previous questions differ for evaluation of sedation products used in the operating room (OR), the intensive care unit (ICU), the emergency department (ED), and the gastrointestinal (GI) suite?

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm>.

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at <http://www.regulations.gov> and may be viewed at the Division of Dockets Management (see Comments). 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 (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: October 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice advises the public of the published lists of all geographic areas, population groups, and facilities designated as primary medical care, mental health, and dental health professional shortage areas (HPSAs) as of September 1, 2011, available on the Health Resources and Services

Administration (HRSA) Web site at <http://bhpr.hrsa.gov/shortage/index.html>. HPSAs are designated or withdrawn by the Secretary of Health and Human Services (HHS) under the authority of section 332 of the Public Health Service (PHS) Act and 42 CFR part 5.

FOR FURTHER INFORMATION CONTACT:

Requests for further information on the HPSA designations listed below and requests for additional designations, withdrawals, or reapplication for designation should be submitted to Andy Jordan, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, Room 9A-18, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 594-0816, <http://bhpr.hrsa.gov/shortage/index.html>.

SUPPLEMENTARY INFORMATION:

Background

Section 332 of the PHS Act, 42 U.S.C. 254e, provides that the Secretary of HHS shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish a list of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary. HRSA's Bureau of Health Professions (BHP) has the responsibility for designating and updating HPSAs.

Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary health services in or to these HPSAs. NHSC health professionals with a service obligation may serve only in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain training program grants administered by BHP. Many other Federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare and Medicaid Services, certain qualified providers in HPSAs are eligible for increased levels of Medicare reimbursement.

Development of the Designation and Withdrawal Lists

Criteria for designating HPSAs were published as final regulations (42 CFR part 5) in 1980. Criteria then were defined for each of seven health

professional types (primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care). The criteria for correctional facility HPSAs were revised and published on March 2, 1989, in the **Federal Register** (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473). Currently funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

Individual requests for designation or withdrawal of a particular geographic area, population group, or a facility as a HPSA are received and reviewed continuously by BHP. The majority of the requests come from the Primary Care Offices (PCOs) in the State Health Departments, who have access to the on-line application and review system. Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, applicants are expected to share copies of the requests with other interested parties, including the Governor, the State Primary Care Association and state professional associations for their comments and recommendations.

Annually, lists of designated HPSAs are provided to all PCOs, state medical and dental societies and others, with a request to review and update the data on which the designations are based. Emphasis is placed on updating those designations that are more than 3 years old or where significant changes relevant to the designation criteria have occurred.

Recommendations for possible additions, continuations, revisions or withdrawals from a HPSA list are reviewed by BHP, and the review findings are provided by letter to the agency or individual requesting action or providing data, with copies to other interested organizations and individuals. These letters constitute the official notice of designation as a HPSA, rejection of recommendations for HPSA designation, revision of a HPSA designation, and/or advance notice of pending withdrawals from the HPSA list. Designations (or revisions of designations) are effective as of the date of the notification letter from BHP. Proposed withdrawals become effective only after interested parties in the area affected have been afforded the opportunity to submit additional information to BHP in support of its continued or revised designation. If no new data are submitted, or if BHP review confirms the proposed withdrawal, it becomes effective upon publication in the **Federal Register** of the lists of HPSAs that do not include