Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

Animal Drug User Fee Cover Sheet; FDA Form 3546 (OMB Control Number 0910–0539)—Extension

Under section 740 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j–12), as amended by ADUFA, FDA has the authority to assess and collect for certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet (FDA Form 3546) is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C Act as amended by ADUFA	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
740(a)(1), FDA Form 3546 (Cover Sheet)	76	1	76	1	76
Total					76

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

Respondents to this collection of information are new animal drug applicants or manufacturers. Based on FDA's database system, there are an estimated 140 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 2008. The estimated hours per response are based on past FDA experience with the various submissions. The hours per response are based on the average of these estimates.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29820 Filed 11–26–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0547]

Clinical Development Programs for Sedation Products; Request for Assistance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups. FDA is inviting any interested party, or parties, to facilitate an evaluation of critical fundamentals of the science related to sedation products by conducting and managing a coordination of activities that will bring together experts in the field, including from academia, patient organizations, and industry. The first step in this process would be for the party or parties to plan and hold one or more public meetings to discuss these issues. FDA intends to take into account the information provided from these activities as we develop FDA guidance on clinical development programs for sedation products. We intend to submit to the docket all the information received in response to this notice so that interested parties may be fully informed.

DATES: Submit electronic or written comments on this notice by January 28, 2011.

ADDRESSES: Submit electronic comments on this notice 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.

FOR FURTHER INFORMATION CONTACT: Sara E. Stradley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3162, Silver Spring, MD 20993–0002, 301–796–1298, FAX:*301–796–9713, e-mail: sara.stradley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Because of the need for more information on the development of products intended to be used in humans for sedation in hospital and outpatient settings, FDA is requesting assistance from the public in conducting scientific analyses for the purpose of further understanding the physiology of sedation and clinical trial design issues related to the development of sedation products.

II. Request for Assistance

FDA is inviting any interested group or consortium of interested groups from academia, industry, practitioners, as well as patients and their representatives to conduct and manage the coordination of a critical evaluation of certain fundamentals of the science related to sedation products. Initially, the party or parties would organize and hold one or more public meetings or workshops to discuss relevant questions associated with the spectrum of sedation, particularly as it relates to procedural and intensive care unit (ICU) sedation, as well as associated clinical trial design issues. FDA believes that a public meeting would help solicit feedback from all parties leading to conceptual advances and a discussion of such advances in a concept paper. This discussion would take into account challenges involved in assessment of sedation and emphasize the rationale for various approaches to key clinical trial design issues involving sedation products. The effort would ultimately lead to developing a draft guidance that would be issued by FDA for broad public comment before finalization, consistent with FDA's good guidance practices regulation (21 CFR 10.115).

III. Suggestions

FDA welcomes other suggestions of activities that could be undertaken as part of this guidance development effort.

IV. Possible Questions/Issues o Be Considered

To provide a starting point for discussion, FDA has developed a list of some key concepts that the interested parties may want to consider for discussion at the meeting as follows:

1. Currently, sedation is studied primarily in the procedural and ICU settings. Procedural sedation may involve an outpatient setting, and may require the institution of Monitored Anesthesia Care (MAC). There is great interest among health care providers with varied medical backgrounds in sedation for surgical and diagnostic procedures in the outpatient setting. What generally constitutes MAC, and what qualifies a product for MAC? How should the need for MAC be assessed in clinical trials involving sedation products?

2. Assessment of procedural sedation involves conducting clinical trials in a wide range of diagnostic and surgical procedures. What surgical and diagnostic procedures are of particular value in assessing the procedural sedation indication? Are there certain procedures that should be evaluated for every product that seeks the procedural sedation indication, or can the range of trials be governed by the pharmacologic profile of the product? Should the scope of the sedation guidance apply to settings other than procedural or ICU sedation?

3. There are patient subgroups in which the use of sedation products should be particularly evaluated. For example, pediatric and geriatric age groups often require dose adjustment because of varying metabolic needs and other clinical parameters. In addition, dose adjustment may be required in patients with renal and hepatic impairment. Are there other patient subgroups that require specific evaluation in clinical trials involving sedation products?

4. Sedation products usually are used as infusions that are titrated to achieve the desired sedation effect. What are optimal trial designs for sedation products? Should clinical trials involving sedation products be placebo-controlled or active-controlled? Currently, Midazolam, Propofol, Ketamine, and Dexmedetomidine are commonly used sedation products. Of these, Midazolam is the most commonly used active comparator in sedation product trial designs. Is it possible to accurately predict the actual size of the treatment effect based on use of Midazolam or other commonly used sedation products? Although trial designs involving these products are believed to be predictive, it may not be possible to generalize from them. If active- and placebo-controlled product trial designs are not optimal, what alternative designs can be used to support sedation claims? Would dose-escalation comparative trial designs be useful in studying sedation products?

5. How is sedation defined and what are appropriate outcome measures to assess sedation? At present, there is diverse opinion among health care providers regarding the definition of sedation. For example, is the assessment of anxiolysis and agitation a separate entity or is it contained within the spectrum of sedation itself? Should this depend upon the known pharmacologic profile of the product? Currently, the primary efficacy endpoint in sedation clinical trials is usually assessed using sedation scales. Commonly used sedation scales include the Ramsey Sedation Scale, Richmond Agitation and Sedation Scale, and Mean Observer's Assessment of Agitation/Sedation Scale. How appropriate is the use of such sedation scales in clinical trials involving sedation products? Should all sedation scales be standardized and validated?

6. Sedation scales are used for assessing the primary efficacy endpoint for sedation products. What are meaningful secondary efficacy endpoints in such trials? Are subjective and objective assessments of memory, recall, anxiety, agitation, delirium, among others, appropriate as efficacy endpoints? Which of these efficacy endpoints should be considered clinically significant? If so, what outcome measures and trial designs should be used? Specifically, how should anxiolysis and agitation be assessed within the realm of products primarily indicated for sedation purposes and not to treat an anxiety disorder or agitation? Should there be different scales for assessing each component, or can the assessment be contained within the spectrum of sedation using an appropriate scale? Further, is an accurate assessment of anxiolysis feasible given the multiple variables that can affect anxiety in a procedural sedation setting that would have to be standardized (*e.g.,* physician and practice setting profile, pre-procedure anticipatory patient prepping, individual thresholds for anxiety)?

7. ICU sedation products are often used for periods longer than 24 hours. Should an ICU sedation indication include a short-term (less than 24 hours) and long-term (more than 24 hours) use assessment for purposes of efficacy and safety? Long-term use may be associated with tolerance/tachyphylaxis and a dose-related increase in adverse effects. What should the size and duration of exposure of the safety database be for sedation products?

V. Comments

Interested persons should submit comments and expressions of interest in conducting and managing a critical evaluation to the Division of Dockets Management (*see* **ADDRESSES**). 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.

Dated: November 17, 2010.

Leslie Kux,

Acting Assisitant Commissioner for Policy.

[FR Doc. 2010–29927 Filed 11–26–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0565]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Clostridium difficile; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Clostridium difficile*." This draft guidance document describes FDA's recommendations concerning 510(k) submissions for various types of in vitro diagnostic devices (IVDs) intended to be used for detecting *Clostridium difficile* (*C. difficile*). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 28, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Clostridium difficile*" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Stephen Lovell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4435, Silver Spring, MD 20993–0002, 301–796–6968.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance includes recommendations concerning 510(k) submissions for various types of (IVDs) intended to be used for detecting *C. difficile.* The document is a revision of "Review Criteria for Assessment of Laboratory Tests Directed at Assisting in the Diagnosis of *C. difficile* Associated Disease" issued on May 31, 1990. It is updated to include new issues and technologies identified since the 1990 guidance. Such methods include detection of *C. difficile* nucleic acids (*e.g., C. difficile* toxin B gene by nucleic acid amplification methods such as the Real-Time Polymerase Chain Reaction technique).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the Agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection of *C. difficile.* It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive "Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Clostridium difficile,*" you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1715 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 42 CFR section 493.15 have been approved under OMB control number 0910–0598; the collections of information in 21 CFR section 50.23 have been approved under OMB control number 0910–0586; and the collections of information in 21 CFR section 56.115 have been approved under OMB control number 0910–0130.

V. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. 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.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29794 Filed 11–26–10; 8:45 am]

BILLING CODE 4160–01–P