ESTIMATE OF ANNUALIZED BURDEN TABLE—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
Enrolled Participant-CSU	Acceptability Survey	260	1	10/60	43
Enrolled Participant-PHMC	Immediate Follow-Up Assessment	225	1	30/60	113
Enrolled Participant-Nova	Immediate Follow-Up Assessment	216	1	30/60	108
Enrolled Participant-CSU	Immediate Follow-Up Assessment	234	1	30/60	117
Enrolled Participant-PHMC	3 month Follow-Up Assessment	200	1	1	200
Enrolled Participant-Nova	3 month Follow-Up Assessment	192	1	1	192
Enrolled Participant-CSU	3 month Follow-Up Assessment	208	1	1	208
Total					2,250

Dated: January 20, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–1650 Filed 1–26–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0026]

Draft Guidance for Industry on Assessment of Abuse Potential of Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Assessment of Abuse Potential of Drugs." This draft guidance is intended to assist sponsors who are developing drug and other medical products with the potential for abuse that may need to be scheduled under the Controlled Substances Act. Drugs with abuse potential generally include drugs that affect the central nervous system, drugs that are chemically or pharmacologically similar to other drugs with known abuse potential, and drugs that produce psychoactive effects such as sedation, euphoria, or mood change.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 29, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Corinne P. Moody, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5144, Silver Spring, MD 20993–0002, 301–796–5402.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Assessment of Abuse Potential of Drugs." Under the Federal Food, Drug, and Cosmetic Act, an abuse potential assessment is part of the general evaluation of the safety and efficacy of a drug to be used under medical supervision. If a drug has abuse potential, the Secretary of Health and Human Services (HHS) is required under the Controlled Substances Act of 1970 (CSA) to make a recommendation for scheduling to the Drug Enforcement Administration (DEA). The regulatory responsibilities for this process are described in Title 21 United States Code (U.S.C.) 811, with delegation of authority to FDA from HHS. The Controlled Substance Staff (CSS) of FDA performs the scientific evaluation of the abuse potential of a drug for HHS, in consultation with the National Institute on Drug Abuse (NIDA), as described in a Memorandum of Understanding (MOU) of March 8, 1985 (50 FR 9518).

When a sponsor submits a marketing application for a drug with abuse potential to FDA for review, the sponsor is required to propose a CSA schedule and provide a basis for this proposal (21 CFR 314.50(d)(5)(vii)). The sponsor's proposal is considered by the agency during its evaluation of the drug's abuse potential. At the time a marketing application is submitted to FDA for review, the sponsor signs a statement agreeing not to market the product until the DEA makes a final scheduling decision.

FDA prepares a scientific analysis with a recommendation for scheduling, based on the submission of the sponsor that includes a scientific and medical evaluation of all relevant and available data, an assessment of the public health risk, and a proposal for scheduling. This recommendation is forwarded to DEA for consideration in the decision on final scheduling of the drug. Scheduling results in specific regulatory requirements relating to the drug's labeling, prescribing, advertising, manufacturing, promotion, marketing, and use in the practice of medicine. Not following these requirements can result in criminal penalties.

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 assessing abuse potential of drugs. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any

mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: January 21, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1516 Filed 1–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0420] (formerly Docket No. 2007D–0365)

Guidance for Industry on the Use of Mechanical Calibration of Dissolution Apparatus 1 and 2—Current Good Manufacturing Practice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2—Current Good Manufacturing Practice (CGMP)." This guidance recommends an alternative method for manufacturers to comply with FDA's CGMP regulations that require laboratory apparatus be calibrated at suitable intervals in accordance with established written specifications. The guidance is intended to aid drug manufacturers (including ancillary testing laboratories) in calibrating U.S. Pharmacopeia (USP) Dissolution Apparatus 1 and 2 to help assure that critical parameters associated with the dissolution apparatus meet certain mechanical calibration (MC) tolerances.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Larry A. Ouderkirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4228, Silver Spring, MD 20993–0002, 301–796–1585.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2—Current Good Manufacturing Practice (CGMP)." The guidance recommends an alternative method for manufacturers to comply with the CGMP regulations that require laboratory apparatus be calibrated at suitable intervals in accordance with established written specifications (§§ 211.160(b)(4) and 211.68 (21 CFR 211.160(b)(4) and 211.68)).

Historically, both MC and chemical (tablet) calibration procedures have been employed to assure that reproducible and repeatable data are obtained with dissolution test apparatus. Recent studies performed in FDA and USP laboratories have identified several significant sources of variation within Apparatus 1 and 2 that can be minimized by employing an enhanced MC procedure. The enhanced MC procedure recommended in the guidance can be used as an alternative to the current Apparatus Suitability procedure for USP Dissolution Apparatus 1 and 2 described in USP General Chapter <711> *Dissolution* that employs basic MC with a performance verification test (PVT) using USP Reference Standard tablets.

In the **Federal Register** of October 19, 2007 (72 FR 59298), FDA published a notice announcing the availability of a draft guidance entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2—Current Good Manufacturing Practice (CGMP)." The notice gave interested persons an opportunity to submit comments by January 17, 2008. Comments received during the comment period have been carefully reviewed, and changes were made to the draft guidance in an effort to make the document clearer. Also, as a result of the received comments, the guidance provides advice on controlling the following recognized sources of significant variability in dissolution testing: Dissolved gases, vibration, and vessel dimensions.

In finalizing this guidance, FDA has made changes to the draft guidance to reflect the most recent changes to USP General Chapter <711> *Dissolution*. On August 1, 2007, USP revised its Chapter <711> as follows: (1) Changed the terminology "calibrator tablets" to "reference standard (RS) tablets," which is the term used to describe tablets used to establish system suitability; and (2) renamed the "Apparatus Suitability Test, Apparatus 1 and 2" to "Performance Verification Test, Apparatus 1 and 2." In making these revisions, USP has explicitly stated, "USP's RS tablets are not calibrator tablets."[1] USP has also announced its intention as of December 1, 2009, to discontinue use of its Salicylic Acid Tablets RS in the Performance Verification Test for Dissolution Apparatus 1 and 2 in <711> (but USP will retain use of its Prednisone Tablets RS). Although USP <711> establishes critical tolerances and parameters for dissolution apparatus, it does not describe enhanced MC practices that can optimize and assure consistent apparatus performance. In October 2007, USP posted to its Web site a "toolkit" to aid practitioners in performing apparatus MC. However, we note that neither the mechanical tolerances specified in USP <711> nor the MC procedure described in the USP toolkit is as comprehensive or stringent as the enhanced MC procedure recommended in the agency guidance.

The CGMP regulations in §§ 211.160(b)(4) and 211.68 require that laboratory apparatus (mechanical equipment used in manufacturing) be calibrated at suitable intervals in accordance with an established written program of scheduled procedures containing provisions for remedial actions. The enhanced MC procedure recommended in the agency guidance satisfies these CGMP requirements and thus can be used as an alternative to the Apparatus Suitability procedure described in USP <711>. Furthermore,

[1] Deng G., A. J. Ashley, W. E. Brown, et al., 2008, "The USP Performance Verification Test, Part I: USP Lot P Prednisone Tablets—Quality Attributes and Experimental Variables Contributing to Dissolution Variance," *Pharmaceutical Research*; 25(5): 1100–1109.