Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles—21 CFR 514.1(b)(7–8) (OMB Control No. 0910–0575)—Extension

In the **Federal Register** of February 17, 2006 (79 FR 8596), FDA's Center for Veterinary Medicine issued a guidance entitled ''Guidance for Industry # 171, Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles'' to address a perceived need for Agency guidance in its work with the animal health industry. This guidance describes the procedures that the Agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

The Generic Animal Drug and Patent Term Registration Act of 1988 (Pub. L. 100–670) permitted generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision. The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: ''USP definition'' approach or ''Dosage adjusted'' approach. The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as shown in tables 1 and 2 of this document. The source of the data is records of generic drug applications over the past 10 years.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS [1]

	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Same formulation/manufacturing process approach	1	1	1	5	5
Same API/solubility approach	5	5	5	10	50
Total					55

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES [1]

	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Same formulation/manufacturing process approach	2	2	2	5	10
Same API/solubility approach	10	10	10	20	200
Total					210

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

Dated: January 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00207 Filed 1–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0505]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455

Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On September 30, 2014, the Agency submitted a proposed collection of information entitled ''Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0623. The approval expires on November 30, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00204 Filed 1–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0092]

Study Data Technical Conformance Guide and Data Standards Catalog; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Study Data Technical Conformance Guide, Version 2.0 (Guide), and an update to the Data Standards Catalog (Catalog). The Guide supplements the final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data guidance) and provides specifications and recommendations for, as well as general considerations on, submitting standardized study data using FDA-supported data standards specified in the Catalog. The Guide is intended to complement and promote interactions between sponsors and FDA review divisions.

DATES: Submit either electronic or written comments on these documents at any time.

ADDRESSES: Submit written requests for a copy of the Study Data Technical Conformance Guide and the Data Standards Catalog 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 electronic comments on the guidance 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: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002, 301–796–5333, *ronald.fitzmartin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of Version 2.0 of the Guide and an update to the Catalog. The Guide supplements the final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*), and provides technical recommendations to sponsors for the electronic submission of standardized animal and human study data and related information contained in certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologic license applications (BLAs), and investigational new drug applications (INDs). The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (which was added by section 1136 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144)) for standardized study data contained in NDA, ANDA, BLA, and IND submissions.

The Guide is intended to complement and promote interactions between sponsors and FDA review divisions. It is not intended to replace the need for sponsors to communicate directly with review divisions regarding data standards implementation approaches or issues.

The Guide is organized as follows:

Section 1: ''Introduction''—provides information on regulatory policy and guidance background, purpose, and document control.

Section 2: ''Planning and Providing Standardized Study Data''—recommends and provides details on preparing an overall study data standardization plan, a study data reviewer's guide, and an analysis data reviewer's guide.

Section 3: ''Exchange Format—Electronic Submissions''—presents the specifications, considerations, and recommendations for the file formats currently supported by FDA.

Section 4: ''Study Data Submission Format: Clinical and Nonclinical''—presents general considerations and specifications for sponsors using, for example, the following standards for the submission of study data: Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), and Standard for Exchange of Nonclinical Data (SEND).

Section 5: ''Therapeutic Area Standards''—presents supplemental considerations and specific recommendations when sponsors submit study data using FDA-supported therapeutic area standards.

Section 6: ''Terminology''—presents general considerations and specific recommendations when using controlled terminologies/vocabularies for clinical trial data.

Section 7: ''Electronic Submission Format''—provides specifications and recommendations on submitting study data using the electronic Common Technical Document format.

Section 8: ''Data Validation and Traceability''—provides general recommendations on conformance to standards, data validation rules, data traceability expectations, and legacy data conversion.

In the **Federal Register** of February 6, 2014 (79 FR 7201), FDA announced the availability of Version 1.0 of the Study Data Technical Conformance Guide. The comment period on the Guide ended on May 7, 2014. We reviewed all comments received and revised it accordingly. Updates to Version 2.0 include, but are not limited to:

Section 2: Added a subsection to include an Analysis Data Reviewer's Guide.

Section 3: Clarified dataset sizes, column lengths, special characters for variables, and datasets.

Section 4: Clarified general considerations and domain specifications for SDTM and ADaM.

Section 6: Clarified a number of subsections, including controlled terminology, medications, pharmacologic class, and indication, and added a World Health Organization Drug Dictionary.