TABLE 1—NADAS: ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.5(b), (d), and (f) Requesting presubmission conferences	169	0.41	69	50	3,450
514.1 and 514.6 Applications and amended applications	169	0.07	12	212	2,544
514.8(b) Manufacturing changes to an approved application	169	2.22	375	35	13,125
514.8(c)(1) Labeling and other changes to an approved application	169	0.06	10	71	710
514.8(c)(2) and (3) Labeling and other changes to an approved application	169	0.72	121	20	2,420
514.11 Submission of data, studies and other information	169	0.08	14	1	14
558.5(i) Requirements for liquid medicated feed	169	0.01	1.7	5	8.5
514.1(b)(8) and 514.8(c)(1) [2] Evidence to establish safety and effectiveness	169	0.15	25	90	2,250
FDA Form 356V	169	4.37	739	5	3,695
Total					28,217

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Based on the number of sponsors subject to animal drug user fees, FDA estimates that there was an average of 169 annual respondents during the 5 fiscal years, from October 1, 2008 through September 30, 2012, on which these estimates were made. We use this estimate consistently throughout the table and calculate the ''total annual responses'' by multiplying the number of responses per respondent by number of respondents.

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28199 Filed 11–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0847]

Draft Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed.'' The draft guidance announced in this notice is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in fulfilling responsibilities related to reviewing the qualifications of investigators, adequacy of research sites, and the determination of whether an investigational new drug (IND) application or investigational device exemption (IDE) is needed in order to assure the protection of the rights and welfare of human subjects in clinical investigations.

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 either electronic or written comments on the draft guidance by January 22, 2013.

ADDRESSES: Submit written requests for single copies of this 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 (1–888–463–6332 or 301–796–3400); or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or 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. 4622, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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: Doreen Kezer, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5109, Silver Spring, MD 20993, 301–796–8524.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed.'' This guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of FDA-regulated

products in determining that the proposed research satisfies the criteria for approval contained in 21 CFR 56.111, that ''* * * the risks to subjects are minimized * * * and reasonable in relation to anticipated benefits, if any, to subjects * * *.'' In particular, the guidance addresses the IRB's role in reviewing: (1) The qualifications of investigators, (2) the adequacy of the research site, and (3) the determination of whether an IND/IDE is needed. When finalized, this guidance will supersede Question 56 in FDA's January 1998 guidance entitled ''Institutional Review Boards Frequently Asked Questions—Information Sheet Guidance for Institutional Review Boards and Clinical Investigators.'' [1]

FDA is issuing this as a draft guidance. Although many of these recommendations have appeared in other FDA guidance documents, FDA has compiled the information here in order to assure that all IRBs are aware of and have access to it. The guidance also explains how IRBs may efficiently fulfill these important responsibilities.

To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts and in consultation with OHRP. In addition, FDA acknowledges HHS's publication of the advanced notice of proposed rulemaking (ANPRM), ''Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,'' in the **Federal Register** of July 26, 2011 (76 FR 44512). In the ANPRM, HHS sought comment on whether the Federal human subject protection regulations should be modified in a number of ways. In finalizing this draft guidance, ''IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed,'' FDA intends to consider relevant public comments submitted in response to both the draft guidance and the ANPRM.

The draft guidance is being issued consistent with FDA's Good Guidance Practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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.

[1] See *http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm#GeneralQuestions.*

II. The Paperwork Reduction Act of 1995

This draft guidance includes information collections provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115 have been approved under OMB control number 0910–0130; the collections of information under 21 CFR Part 312 have been approved under OMB control number 0910–0014; and the collections of information under 21 CFR Part 812 have been approved under OMB control number 0910–0078. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm* or *http://www.regulations.gov.*

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28149 Filed 11–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0643]

Draft Guidance for Industry on Electronic Source Data in Clinical Investigations; 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 ''Electronic Source Data in Clinical Investigations.'' This document revises and updates the draft guidance entitled ''Electronic Source Documentation in Clinical Investigations.'' This revised draft document provides guidance to sponsors, contract research organizations (CROs), data management centers, clinical investigators, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations. The revised draft guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of electronic source data.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within January 22, 2013.

ADDRESSES: Submit written requests for single copies of the revised 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; Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448; 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; and Office of Critical Path Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4173, Silver Spring,