TABLE 1—ESTIMATED REPORTING BURDEN [1]—Continued

Secure Supply Chain Pilot Program	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Total	.....	.....	.....	.....	1,756

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Secure Supply Chain Pilot Program	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours/ week	Total hours per year
Secure Supply Chain Pilot Program Records	100	5	500	1	500	26,000

[1] There are no capital or operating costs associated with this recordkeeping.

Dated: June 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14990 Filed 6–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012–D–0304]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis.'' This draft guidance document describes a means by which implanted blood access devices may comply with the requirement of special controls for class II devices. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 18, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis'' to the Division of Small Manufacturers,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 draft guidance.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993–0002, 301–796–5616.

I. Background

This draft guidance document was developed as a special control guidance to support the reclassification of implanted blood access devices into class II (special controls). This draft guidance document will serve as the special control for implanted blood access devices. Section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides that the Agency may initiate the reclassification of a device. This classification will be a reclassification of the device. FDA must publish a notice in the **Federal Register** announcing this reclassification. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify this device type from class III into class II (special controls), under section 513(e) of the FD&C Act (21 U.S.C. 360c(e)).

FDA is issuing this guidance document as a level 1 draft guidance document. FDA will consider any comments that are received within 90 days of the issuance of this notice to determine whether to revise the guidance document.

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the recommendations described in this draft guidance document, when finalized, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of implanted blood access devices classified under § 876.5540(b)(1) (21 CFR 876.5540(b)(1)). If classified as a class II device under § 876.5540(b)(1), implanted blood access devices will need to comply with the requirement for special controls; manufacturers will need to address the issues requiring special controls as identified in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

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 ''Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis,'' you may either send an email 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 1781 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. 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 are currently approved under OMB control number 0910–0120; the collections of information in 21 CFR 56.115 are currently approved under OMB control number 0910–0130; the collections of information in 21 CFR part 812 are currently approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 801 are currently approved under OMB control number 0910–0485.

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: June 15, 2012.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2012–15025 Filed 6–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0419]

Draft Guidance for Industry on Active Controls in Studies To Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals; 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 #204 entitled ''Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals.''

This draft guidance advises industry on the use of active controls in studies intended to provide substantial evidence of effectiveness of new animal drugs for use in companion animals. The intent of the guidance is to provide information to clinical investigators who conduct studies using active controls and have a basic understanding of statistical principles.

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 August 20, 2012.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that 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: Lisa M. Troutman, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8322, *lisa.troutman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #204 entitled ''Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals.'' The purpose of this draft guidance is to provide information to clinical investigators who conduct studies using active controls and have a basic understanding of statistical principles. The draft guidance advises industry on the use of active controls in studies intended to provide substantial evidence of effectiveness of new animal drugs for use in companion animals. The draft guidance compares studies that use active controls to studies that use either placebo concurrent controls or untreated concurrent controls, and it uses these comparisons to illustrate the advantages and disadvantages of using a study with an active control. Examples are provided to illustrate some of the different outcomes that are possible when employing active controls in studies.

II. Significance of Guidance

This level 1 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 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 514 have been approved under OMB control number 0910–0032.

IV. 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. 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.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: June 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14988 Filed 6–19–12; 8:45 am]

BILLING CODE 4160–01–P