TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
312.7(d)	41	1.4	57	24	1,368
312.23(a) through (f) and 312.120(b), (c)(2), and (c)(3)	433	1.3	563	1,808	1,017,904
312.30(a) through (e)	590	6.8	4,012	284	1,139,408
312.31(b)	263	29.3	7,706	100	770,600
312.32(c) and (d) and 312.56(c)	294	13.7	4,028	32	128,896
312.33(a) through (f) and 312.56(c)	647	2.3	1,488	360	535,680
312.35(a) and (b)	1	1	1	300	300
312.36	6	1	6	16	96
312.38(b) and (c)	117	1.3	152	28	4,256
312.42(e)	74	1.5	111	284	31,524
312.44(c) and (d)	17	1.1	18	16	304
312.45(a) and (b)	60	1.8	108	12	1,296
312.47(b)	43	1.5	65	160	10,400
312.53(c)	348	6.6	2,297	80	183,760
312.54(a) and (b)	1	1	1	48	48
312.55(b)	138	2.5	345	48	16,560
312.56(b) and (d)	14	1.6	22	80	1,760
312.58(a)	8	1	8	8	64
312.64(a) through (d)	6,003	3.5	21,010	24	504,240
312.70(a)	6	1	6	40	240
312.110(b)	21	1	21	75	1,575
312.130(d)	1	1	1	8	8
Total					4,350,287

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) [2]	Total hours
312.52(a)	139	1.4	195	2	390
312.57(a) and (b)	433	2.6	1,126	100	112,600
312.62(a)	5,570	1	5,570	40	222,800
312.62(b)	5,570	10	55,700	40	2,228,000
312.160(a)(3)	146	1.4	204	30/60	102
312.160(c)	146	1.4	204	30/60	102
Total					2,563,994

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

Dated: May 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11540 Filed 5–10–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0272]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for Chlamydia Trachomatis and/or Neisseria Gonorrhoeae: Screening and Diagnostic Testing; 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 "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for *Chlamydia Trachomatis* and/or *Neisseria Gonorrhoeae:* Screening and Diagnostic Testing." This draft guidance document provides industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of in vitro diagnostic devices (IVDs) intended for *C. trachomatis* and/or *N. gonorrhoeae* screening and diagnostic testing using nucleic acid based assays. 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 of 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 9, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for *Chlamydia Trachomatis* and/or *Neisseria Gonorrhoeae:* Screening and Diagnostic Testing" 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 (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: Kathleen Whitaker, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5500, Silver Spring, MD 20993–0002, 301–796–6208.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of IVDs intended for *C. trachomatis* and/or *N. gonorrhoeae* screening and diagnostic testing using nucleic acid based assays. These devices are used to aid in the diagnosis of urogenital *C. trachomatis* and *N. gonorrhoeae* infection. They include devices that detect one specific organism, as well as devices that may detect both organisms with or without further differentiation.

This draft guidance provides detailed information on the types of studies FDA recommends to support class I and class II premarket submissions for these devices. The draft guidance includes a list of *C. trachomatis* and *N. gonorrhoeae* strains recommended for analytical sensitivity studies and a list of micro-organisms recommended for analytical specificity studies. This document also addresses recommendations for fulfilling labeling requirements applicable to all in vitro diagnostic devices intended to screen for, or aid in the diagnosis of, *C. trachomatis* and/or *N. gonorrhoeae* directly from human specimens.

This document is limited to studies intended to establish the performance characteristics of devices that detect chlamydial and/or gonococcal nucleic acid. It does not address detection of serological response from the host to bacterial antigens, nor does it address establishing performance of non-chlamydial or non-gonococcal components of multianalyte or multiplex devices.

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 *C. trachomatis* and/or *N. gonorrhoeae* screening and diagnostic testing. 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 *Chlamydia Trachomatis* and/or *Neisseria Gonorrhoeae:* Screening and Diagnostic Testing," 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 1733 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 21 CFR parts 56.115 have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been 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: May 6, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–11532 Filed 5–10–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0621]

Proposal To Withdraw Approval for the Breast Cancer Indication for Bevacizumab; Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of hearing.

SUMMARY: The Food and Drug Administration (FDA) is granting a hearing to Genentech, Inc. (Genentech), on the Center for Drug Evaluation and Research's (CDER's) proposal to withdraw approval of the breast cancer indication for bevacizumab (Avastin). Genentech is the sponsor for Avastin. Genentech and CDER are the parties to the hearing. The issues to be discussed and resolved at the hearing relate directly to the statutory and regulatory standard for FDA to withdraw accelerated approval of the metastatic