Estimated Annual Reporting Burden for Biological Products in the Center for Biologics Evaluation and Research

Under § 312.23(a)(7)(iv)(e) and 601.2(a), INDs and BLAs must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 2008, FDA received 245 INDs from 180 sponsors, 28 BLAs from 13 applicants, and 972 BLA supplements to license applications from 173 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA estimates that it received approximately 370 claims for categorical exclusion as required under § 25.15(a) and (d), and 2 EAs as required under § 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim for categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product.

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.15(a) and (d)	210	1.76	370	8	2,960
25.40(a) and (c)	2	1	2	3,400	6,800
Total					9,760

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

Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications (INADs); and 21 CFR 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or § 25.33 or an EA under § 25.40. In 2008, FDA's Center for Veterinary Medicine received approximately 676 claims for categorical exclusion as required under § 25.15(a) and (d), and 8 EAs as required under § 25.40(a) and (c). FDA estimates that it takes sponsors/applicants approximately 5 hours to prepare a claim for a categorical exclusion and an average of 2,160 hours to prepare an EA.

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.15(a) and (d)	65	10.4	676	5	3,380
25.40(a) and (c)	6	1.3	8	2,160	17,280
Total					20,660

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

TABLE 6.—COMBINED ESTIMATED ANNUAL TOTAL BURDEN HOURS FOR ALL CENTERS

Total	193,797

Dated: August 28, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21724 Filed 9–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10295]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare and Medicaid Services, Department of Health and Human Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting emergency approval under 5 CFR 1320.13(a)(2)(iii), as we believe that the use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed for annual reports to Congress as required under sections 5001 and 5004 of the Recovery Act.

1. Type of Information Collection Request: New collection; *Title of Information Collection:* Recovery Act—Reporting Requirements for States Under FMAP Increase and TMA Provisions; *Use:* The American Recovery and Reinvestment Act of 2009 (Recovery Act), Public Law 111–5, requires that States submit quarterly reports to the Secretary of Health and Human Services in accordance with section 5001 Temporary Increase of Medicaid Federal Medical Assistance Percentage (FMAP) and section 5004(d) Extension of Transitional Medical Assistance (TMA). The reports under section 5001 are required for the period of October 1, 2008–September 30, 2011. The reports under section 5004 are required beginning on July 1, 2009 until the Federal authority for TMA coverage sunsets (now scheduled to sunset on December 31, 2010). Each State Medicaid agency will submit its quarterly reports to the appropriate Regional Office of CMS. The reports will be compiled and summarized for annual reports to Congress. *Form Number:* CMS–10295 (OMB#: 0938–New); *Frequency:* Reporting—Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 200; *Total Annual Hours:* 600. (For policy questions regarding this collection contact Richard Strauss at 410–786–2019. For all other issues call 410–786–1326.)

CMS is requesting OMB review and approval of this collection by *October 5, 2009,* with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by the noted deadline below.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by October 9, 2009:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number (CMS–10295), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

and,

OMB Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503. *Fax Number:* (202) 395–6974.

Dated: August 31, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–21674 Filed 9–8–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0386]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses; 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 the Detection or Detection and Differentiation of Human Papillomaviruses.'' FDA is issuing this draft guidance to inform industry and agency staff of its recommendations for analytical and clinical performance studies to support premarket submissions for in vitro diagnostic devices intended for the detection or detection and differentiation of human papillomaviruses.

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 December 8, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses'' 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. 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 written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kate Simon, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5552, Silver Spring, MD 20993, 301–796–6204.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document recommends studies that may be used to establish the analytical and clinical performance of in vitro diagnostic devices (IVDs) for the detection or detection and differentiation of human papillomaviruses (HPV) in cervical specimens. This guidance is limited to studies intended to establish the performance characteristics of in vitro diagnostic HPV devices that are used in conjunction with cervical cytology for cervical cancer screening. It does not