EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost	Annualized cost
Publication of Results	149,476	66,434
Project Management	70,313	31,250
Overhead	175,095	77,820
Total	600,055	266,691

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 3, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–1169 Filed 1–24–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0370]

Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance entitled "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010" dated August 2010, that was announced in the **Federal Register** of August 25, 2010. FDA now intends to complete the notice and comment rulemaking process for the Patient Protection and Affordable Care Act of 2010 (hereinafter "section 4205") before initiating enforcement activities based, in part, on extensive comments on the draft guidance submitted to the Agency. FDA believes that this approach to implementing section 4205 will minimize uncertainty and confusion among all interested persons.

DATES: The withdrawal is effective January 25, 2011.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Foods Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 25, 2010 (75 FR 52426), FDA announced the availability of a draft guidance entitled "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010." As stated in the draft guidance, certain provisions of section 4205 became requirements immediately upon enactment of the law. FDA recognized that industry may need additional guidance from the Agency and time to comply with these provisions. As a result, FDA stated that it expected to refrain from initiating enforcement action against establishments that are subject to, but not in compliance with, the provisions of section 4205 that became requirements immediately upon enactment of the law until a time period established in the draft guidance. FDA also stated that it anticipated issuing the guidance in December 2010.

Based, in part, on extensive comments on the draft guidance submitted to the Agency, FDA now intends to complete the notice-and-comment rulemaking process for section 4205 before initiating enforcement activities. As noted in the draft guidance, FDA is required to issue proposed regulations to carry out provisions of section 4205 no later than March 23, 2011. FDA intends to meet this statutory deadline. In the course of developing the proposed rule, the Agency has considered the comments received on the draft guidance. FDA will then review the comments it receives on the proposed rule and issue a final rule expeditiously.

FDA believes that this approach to implementing section 4205 will minimize uncertainty and confusion among all interested persons. The Agency also believes that expeditious completion of the rulemaking process will most rapidly lead to full and consistent availability of the newly required nutrition information for consumers.

For these reasons, FDA is at this time withdrawing the draft guidance entitled "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010."

Dated: January 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1530 Filed 1–21–11; 12:00 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0559]

Guidance for Industry on Process Validation: General Principles and Practices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a guidance for industry entitled "Process Validation: General Principles and Practices." This guidance provides information for the pharmaceutical industry on the elements of process validation for the manufacture of human and animal drug and biological products, including active pharmaceutical ingredients (APIs). The guidance is intended to provide clear and consistent communication of regulatory expectations and to promote voluntary compliance with current FDA requirements. This guidance revises and replaces the guidance for industry entitled "Guideline on General Principles of Process Validation," dated May 1987.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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:

Brian Hasselbalch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4364, Silver Spring, MD 20993–0002, 301–796–3279; or

Grace McNally, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4374, Silver Spring, MD 20993–0002, 301–796–3286; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or

Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8268.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Process Validation: General Principles and Practices." This guidance document provides guidance to the pharmaceutical industry on the elements of process validation for the manufacture of human and animal drug and biological products, including APIs.

This guidance describes process validation activities in three stages:

- In Stage 1, Process Design, the commercial process is defined based on knowledge gained through development and scale-up activities.
- In Stage 2, Process Qualification, the process design is evaluated and assessed to determine if the process is capable of reproducible commercial manufacturing.
- In Stage 3, Continued Process Verification, ongoing assurance is gained during routine production that the process remains in a state of control.

In addition to discussing activities typical of each stage of process validation, the guidance provides recommendations regarding appropriate documentation and analytical methods to be used during process validation.

In the **Federal Register** of November 18, 2008 (73 FR 68431), FDA announced the availability of a draft guidance of the same title and gave interested persons the opportunity to submit comments by January 20, 2009. In the **Federal Register** of February 13, 2009 (74 FR 7237), the Agency reopened the comment period to March 16, 2009. The Agency received public comments from a broad spectrum of the pharmaceutical industry. In response to comments received on the draft guidance, the Agency added a glossary of terms and clarified or added more specific guidance on certain issues.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the general principles and practices of process validation. 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.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 requested in the guidance are covered under FDA regulations at 21 CFR part 211, 21 CFR 314.70, and 21 CFR 601.12 and are approved under OMB control numbers 0910–0139, 0910–0001 and 0910–0338, respectively.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *http://www.regulations.gov.*

Dated: January 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1437 Filed 1–24–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review: Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to