

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
<b>Total .....</b>	<b>600,055</b>	<b>266,691</b>

**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]

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**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**Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Withdrawal of Draft Guidance**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withdrawal of a draft guidance entitled "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act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]

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**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