

Withdrawal of Draft FDA 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

January 21, 2011

The Food and Drug Administration (FDA) today announced the withdrawal of a draft guidance entitled “Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act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 on August 25, 2010. The notice of withdrawal can be found beginning on January 21, 2011 at http://www.ofr.gov/OFRUpload/OFRData/2011-01530_PI.pdf.

FDA issued the draft guidance to provide guidance for industry and State and local governments affected by the enactment of section 4205 of the Patient Protection and Affordable Care Act (Affordable Care Act). As stated in the draft guidance, certain provisions of section 4205 of the Affordable Care Act became requirements immediately upon enactment of the law. FDA also stated that it anticipated issuing the final guidance and enforcement policy in December 2010.

FDA received many comments on the draft guidance and on a public docket which FDA opened to solicit comment. Based, in part, on these comments, FDA now intends to complete the notice and comment rulemaking process for section 4205 before initiating enforcement activities and will not be publishing a final guidance on menu labeling at this time. 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.

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

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