SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “Frequently Asked Questions About Medical Foods; Second Edition.” This draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’s current thinking on medical foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

We originally issued this guidance in May 2007. This draft guidance provides responses to additional questions regarding the definition, labeling, and availability of medical foods and updates to some of the existing responses.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 PRA). The collections of information in sections 101.4, 101.5, 101.15, and 101.105 of 21 CFR part 101 have been approved under OMB control number 0910–0381. The labeling provisions recommended in this draft guidance in response to Question 13 are not subject to review by OMB because they do not constitute a “collection of information” under the PRA. Rather, the recommended labeling is a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

III. Comments

Interested persons may submit either electronic comments regarding this draft guidance to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of 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, and will be posted to the docket at http://www.regulations.gov.