Medication Guide should be required for distribution to each patient when the drug is dispensed. Since the enactment of the Food and Drug Administration Amendments Act of 2007, FDA has, as a matter of policy, considered any new Medication Guide (or safety-related changes to an existing Medication Guide) to be part of a REMS. However, the Agency has the authority to determine, based on the risks of a drug and public health concern, how a Medication Guide should be required when the standard in part 208 is met. Based on the risks and public health concern, the Agency may require:

(1) A Medication Guide in accordance with part 208 that is not part of a REMS or

(2) A Medication Guide in accordance with part 208 and section 505–1 of the FD&C Act that is part of a REMS, which will include other parts of a REMS (such as the timetable for submission of assessments) and possibly other REMS elements (including elements to assure safe use).

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on how FDA intends to exercise enforcement discretion regarding Medication Guide distribution and Inclusion of Medication Guides in REMS. 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. 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.

III. 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This draft guidance refers to previously approved collections of information found in FDA regulations.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 collections of information in §§314.70 and 600.12 have been approved under OMB control numbers 0910–0001 and 0910–0338; the collections of information in part 208 have been approved under OMB control number 0910–0393.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/