elements from E2B(R2) and E2B(R3) and is intended to assist reporters and recipients in implementing systems with special focus on the recommendations for converting back and forth between E2B(R2) and E2B(R3) ICSR reports. The draft E2B(R3) implementation guidance and draft BFC appendix are being issued as a package that includes schema files and additional technical information.

The draft E2B(R3) implementation guidance and BFC appendix are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The documents, when finalized, will represent the Agency’s current thinking on this topic. The documents do not create or confer any rights for or on any person and do 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 and scientific data and information that was submitted. A summary of 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.

III. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.regulations.gov. Submit written comments and scientific data and information to http://www.regulations.gov. Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jane M. Van Doren, Center for Food Safety and Applied Nutrition (HFS—005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2927.