

807, subpart E, OMB control number 0910-0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see

ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: July 17, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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