

other labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The requirement that the bar code be surrounded by sufficient blank space and remain intact under normal conditions of use would help ensure that the bar code can be read easily and accurately so that its safety benefits may be realized.

Because biological products, including blood, are also prescription drug products, the sections of the act discussed elsewhere in this legal authority section provide ample legal authority for promulgating a regulation requiring bar coding for such biological products. There is, however, additional legal authority for the rule's requirements as to biological products. Section 351 of the Public Health Service Act authorizes the imposition of restrictions through regulations "designed to insure the continued safety, purity, and potency" (including effectiveness) of the products. Biological product licenses are to be "issued, suspended, and revoked as prescribed by regulations" (42 U.S.C. 262(d)(1); see §§ 601.4 through 601.6). The bar code requirement for biological drugs, and the machine-readable information requirement for blood and blood products, is designed to insure the continued safe and effective use of licensed biological products. Therefore, if this rule were finalized, we may refuse to approve biologics license applications (BLAs), or may revoke already approved licenses, for biological drug products that do not have such codes.

Additionally, section 361 of the Public Health Service Act authorizes regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. With specific regard to blood and blood products, the requirement for machine readable information will aid in the recall, quarantine and retrieval of units that are at risk of spreading communicable diseases.

After the effective date of any final rule, if a product required by the final rule to bear a bar code does not have such a bar code, the product may be considered adulterated or misbranded under the act and would be subject to regulatory action. Our enforcement actions under the act include seizure, injunction, and prosecution, and violation may result in withdrawal of an NDA or BLA.

IV. Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We describe the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on: (1) Whether the collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Bar Code Label Requirement for Human Drug Products and Blood.

Description: We are proposing a new rule that would require human drug product and biological product labels to have bar codes. The proposed rule would require bar codes on human prescription drug products and OTC drug products that are dispensed pursuant to an order and commonly used in hospitals and would require machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed pursuant to an order and commonly used in hospitals, the bar code would contain the National Drug Code for the product. For blood and blood components, the proposed rule would specify the minimum contents of the machine-readable information approved by the Director of the Center for Biologics Evaluation and Research as

blood centers have generally agreed upon the information to be encoded on the label. The proposed rule would help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Because the Center for Drug Evaluation and Research would have bar code information for drugs subject to a new drug application or abbreviated new drug application to be reported through an annual report, this proposed rule affects the reporting burden associated with § 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii)). Section 314.81(b)(2)(iii) requires the submission of an annual report containing a representative sample of package labels and a summary of labeling changes (or, if no changes have been made, a statement to that effect) since the previous report. Here, the bar code would result in a labeling change. We have previously estimated the reporting burden for submitting labels as currently required under § 314.81(b)(2)(iii), and OMB has approved the collection of information until March 31, 2005 under OMB control number 0910–0001. We are not re-estimating these approved burdens in this rulemaking; we are only estimating the additional reporting burdens associated with the submission of label changes under § 314.81(b)(2)(iii).

Minor label changes for blood and blood products may be reported as part of an annual report, as described in 21 CFR 601.12(f)(3), and we would consider the machine-readable information on blood and blood product labels to be a minor change. We have previously estimated the reporting burden for submitting labels as currently required under § 601.12(f)(3), and OMB has approved the collection of information until August 31, 2005 under OMB control number 0910–3338. We are not re-estimating these approved burdens in this rulemaking; we are only estimating the additional reporting burdens associated with the submission of label changes under § 601.12(f)(3).

Description of Respondents: Persons who manufacture, repack, or relabel prescription drug products or OTC drugs that are dispensed pursuant to an order and commonly used in hospitals, and blood establishments.

We estimate the burden of this collection of information as follows: