UNITED STATES FOOD & DRUG ADMINISTRATION

Labeling Requirements for Human Prescription Drug and Biological Products
21 CFR Part 201, Subparts A and B

OMB Control Nos. 0910-0734, 0910-0537, 0910-0670 and 0910-0572

Request for Non-substantive Change and Request to Discontinue:

Regulations in 21 CFR 201, subparts A and B, set forth specific requirements governing the content and format of labeling for human drug and biological products. The regulations also provide that, upon request, FDA may grant a waiver from certain requirements. Information collection applicable to regulations in 21 CFR 201, subpart C, pertaining to requirements for over-the-counter (OTC) products, is currently approved under OMB control no. 0910-0340. Still, FDA maintains other information collection approvals pertaining to specific aspects of drug and biological drug product labeling, although we continue to evaluate our inventory for ways to increase organizational efficiency.

Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355(o)(4)) provides for safety-related labeling changes based on information that becomes available after approval of the drug or biological product. Section 505(o)(4) of the Act authorizes FDA to require safety labeling changes for prescription drug products with an approved new drug application (NDA) under section 505(b) of the Act; biological drug products with an approved biologics license application (BLA) under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C 262); and prescription drug products with an approved abbreviated new drug application (ANDA) under section 505(j) of the Act, if the NDA reference listed drug (RLD) is not currently marketed. Section 505(o)(4) also prescribes specific time frames for the submission of information and FDA action with regard to safety labeling changes. To help implement these provisions, and assist respondents with applicable statutory and regulatory requirements, we developed the guidance document entitled *"Safety Labeling Changes--Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act,"* (July 2013). The guidance document includes instruction on communicating with FDA regarding labeling changes required under section 505(o)(4) (*Section IV – Procedures*). Currently this information collection is approved under OMB control no. 0910-0734.

We are also requesting to include information collection under 21 CFR § 201.25(d), requiring that manufacturers submit a written request for exemption from applicable bar code requirements. Currently this information collection is approved under OMB control no. 0910-0537. Upon review, we note that ICR 0910-0537 was established for rulemaking in February 26, 2004 (published at 69 FR 9120) to support information collection associated with bar code requirements covered in 21 CFR part 201.

Finally, we request to include the information collection regarding the labeling of drugs that include a hypertension indication. The CV Outcome Claims guidance was recommended to FDA by the Cardiovascular and Renal Drugs Advisory Committee in support of class labeling for cardiovascular outcome claims for drugs that are indicated to treat hypertension. To assist respondents in developing cardiovascular outcome claims for drugs that are indicated to treat hypertension, we developed the guidance document entitled *"Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims (CV Outcome Claims guidance),"* (March 2011). Currently this information collection is approved under OMB control no. 0910-0670.

For efficiency of agency operations, we are requesting to consolidate the related information collection activity and account for burden we attribute to the recommendations found in the referenced guidance

document, as well as burden associated with waiver requests from bar code requirements in 21 CFR part 201. Accordingly, we have adjusted the estimated burden in control number 0910-0572 by 394 responses, 1,758 hours, and $129,150 cost annually to reflect these changes. Upon approval of this request, we intend to discontinue the collections of information currently approved under OMB control numbers 0910-0734, 0910-0537 and 0910-0670.

SUBMITTED February 2022