

UNITED STATES FOOD AND DRUG ADMINISTRATION

Applications for FDA Approval to Market a New Drug

OMB Control No. 0910-0001

Request for Non-Substantive, Non-material Changes to Approved Information Collection:

This information collection supports implementation of section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA), Food and Drug Administration (FDA, the agency, us or we) regulations in 21 CFR part 314, and associated agency guidance.

We are requesting the following:

1. Consolidation of 0910-0759.

By final rule of July 8, 2015 (0910-AH88; 80 FR 38915), FDA established notification requirements regarding the the permanent discontinuance or interruption in manufacturing of marketed prescription drugs for human use without approved new drug applications in 21 CFR part §310.306. The regulation requires all applicants of covered approved drugs or biological products— including certain applicants of blood or blood components for transfusion and all manufacturers of covered drugs marketed without an approved application—to notify FDA electronically of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply (or a significant disruption in supply for blood or blood components) of the product in the United States. Provisions in 21 CFR part 600.82 pertaining to biological products are covered in OMB control no. 0910-0338. Provisions applicable to marketed drugs for human use in 21 CFR part 314.81 (other postmarketing reports) are covered here in OMB control no. 0910-0001. For efficiency of agency operations were are consolidating related information collection applicable to the requirements in 21 CFR 310.306. While we have made no adjustments to our estimated burden, we have included citation to 21 CFR 310.306 in the “Subpart B – Applications” IC. Upon OMB approval of our request we will discontinue control no. 0910-0759.

2. Information Collection Recommendation in Agency Guidance.

Section 314.107(f) requires that Abbreviated New Drug Application (ANDA) or 505(b)(2) applicants notify FDA immediately of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner must also notify FDA of the filing of any legal action for patent infringement. If the patent owner or approved application holder who is an exclusive patent licensee waives its opportunity to file a legal action for patent infringement within the 45-day period, the patent owner or approved application holder may submit to FDA a waiver in the specified format. In the draft guidance document, “*Guidance for Industry: Good ANDA Submission Practices*” (January 2018), attached with this request, FDA recommended that ANDA or 505(b)(2) applicants include a complete copy of the civil action (i.e., a complete copy of the civil complaint) with the notification in 21 CFR 314.107. (See Section III; Part A (p.5): *Patent and Exclusivity Deficiencies; Documentation and Notification of a Legal Action Filing.*) The guidance is intended to assist applicants preparing to submit ANDAs to FDA and

highlights common, recurring deficiencies that may lead to a delay in approval. It also makes recommendations to applicants on how to avoid these deficiencies with the goal of minimizing the number of review cycles necessary for approval. The draft guidance was issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115 which provides for public comment at any time. We intend to finalize the guidance document, also consistent with our GGP regulations, and include the recommendation that a complete copy of the civil action be submitted with notifications under 21 CFR 314.107, however we have made no adjustment to our burden estimate.

Submitted: April 2021