REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

OMB Control No. 0910-0045

Request for non-substantive/non-material changes:

This information collection request (ICR) supports FDA regulations pertaining to the registration of drug producers and the listing of drugs in commercial distribution (21 CFR part 207), including the production and listing of animal drugs. The purpose of the information collection is to enable FDA to identify drug manufacturers and manufacturing operations to facilitate implementation and enforcement of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and to promote and protect the public health. Current requirements provide for electronic reporting and recordkeeping and identify specific content and format elements, including the amount of drug produced and any changes in manufacturing. FDA uses this information to help mitigate and plan for potential shortages.

1. *Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products*. The document entitled, "*Guidance for Industry; Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products (MNPs)"* provides recommendations to manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products for developing a written plan to maintain an adequate supply of MNPs during an emergency that results in high employee absenteeism. The guidance discusses issues such as: (1) identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate a plan (hereafter, "the Plan") and make decisions during the emergency; (2) prioritizing the manufacturer's drug products based on medical necessity; (3) identifying actions that should be taken prior to an anticipated period of high absenteeism; (4) identifying criteria for activating the Plan; (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet a demand for MNPs; (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes; and (7) testing the Plan. The guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. We are requesting to consolidate burden currently approved and accounted for under OMB Control No. 0910-0675 that may result from recommendations found in the subject guidance document, into the instant collection. We are taking this action for efficiency of agency operations with regard to the management of like collection activity. We believe that most respondents of medically necessary products have realized burden associated with recommendations discussed in the guidance, however, to reflect the burden associated with this information collection element, we have adjusted reporting burden to reflect an addition 72 responses and 17,532 hours annually.

2. *Voluntary Reporting of Animal Drug Shortage Information*. The guidance document, "Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency" (May 2020), provides recommendations on the information sponsors should submit to the Center for Veterinary Medicine (CVM) to report and mitigate animal drug shortages for the duration of the public health emergency. Because domestic and foreign establishments that manufacture, repack, or re-label animal drug products in the United States are required to register with the FDA in conjunction with the human drug registration process, we are including this related activity within this information collection. As communicated in the guidance document, the information collection recommendations are voluntary but intended to apply to the reporting of information related to all animal drug shortages, regardless of a drug's status as a medically necessary veterinary product (MNVP). Accordingly, we are requesting to include burden associated with submitting the voluntary information and have added a new information collection element for animal drug shortage reporting to reflect 60 hours and 60 responses annually, to reflect submissions anticipated from 30 respondents.

Accordingly, we have adjusted the estimated burden in control number 0910-0045 by 132 responses, 17,592 hours to reflect these changes. Upon approval of this request, we intend to discontinue the collections of information currently approved under OMB control number 0910-0675.

Dated: December 2022