SUBJECT: Request for Emergency Clearance of the Paperwork Reduction Act Package for the Interim Final Rule regarding Applications for Food and Drug Administration Approval to Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance (Drug Shortages Interim Final Rule)

Request for Emergency Clearance

FDA's Center for Drug Evaluation and Research (CDER) is requesting that a Paperwork Reduction Act (PRA) package for the Interim Final Rule regarding *Applications for Food and Drug Administration Approval to Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance* be approved using the emergency clearance process under 5 C.F.R. § 1320.13(a)(2)(i). Public harm is reasonably likely to ensue if the normal clearance procedures are followed.

Public Harm is Reasonably Likely to Occur if Normal Clearance Procedures are Followed

The interim final rule is essential to ensuring that the FDA receives timely reports from sole manufacturers of discontinuances of certain drug products. These discontinuances often lead to drug shortages. The number of drug shortages annually has tripled from 61 in 2005 to 178 in 2010. Some shortages delay or deny needed care for patients, because they involve critical drugs used to treat cancer, to provide required parenteral nutrition, or to address other serious medical conditions. Cancer alone affects more than 11 million people in the United States annually. Other shortages force providers to prescribe second-line alternatives, which may be less effective and higher risk than first line therapies.

If the FDA receives reports of discontinuances, it can work with the manufacturer and others to prevent the discontinuance from leading to a drug shortage, or, if a shortage does occur, to mitigate the impact of the shortage on patients. In the absence of immediate approval of the information collection in the interim final rule, the Agency will not receive all relevant information on discontinuances and drug shortages, putting the Agency at a serious disadvantage in addressing these shortages and putting many patients at risk.

FDA believes that significant public harm will occur if normal Paperwork Reduction Act (PRA) clearance procedures are followed. In the six months or more it can take to obtain a full PRA clearance to authorize the information collection in the interim final rule, a significant number of patients could be exposed to drug shortage-related harm, including delay of treatment, denial of life saving therapies, or exposure to riskier alternatives. FDA believes that these circumstances can be mitigated or prevented through prompt FDA intervention based on the information provided by manufacturers. Accordingly, FDA is requesting that OMB use its emergency clearance process to **immediately approve** the PRA package for the interim final rule.

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