

21 CFR Part 429**[Docket No. 91N-0173]****RIN 0910-AA07****Fees for Certification of Drugs Composed Wholly or Partly of Insulin****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Interim final rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule to amend its regulations establishing the fee schedule for the insulin certification program. The interim final rule decreases the fees charged for insulin certification services because experience has demonstrated that the current fee schedule does not accurately reflect FDA's actual cost of administering the insulin certification program.

DATES: The interim final rule is effective December 11, 1995, written comments by February 7, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1049.

SUPPLEMENTARY INFORMATION:**I. Introduction**

In 1941, Congress amended the Federal Food, Drug, and Cosmetic Act (the act) to require FDA to certify batches of drugs composed wholly or partly of insulin (Pub. L. 77-366). This amendment created section 506 of the act (21 U.S.C. 356), which requires the agency to provide for the certification of a batch of a drug composed wholly or partly of insulin if the "drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity [that are] * * * necessary to adequately insure safety and efficacy of use * * *." Section 506 of the act also requires FDA to promulgate regulations governing the certification of drugs containing insulin. Uncertified batches of insulin that are shipped in interstate commerce are misbranded under section 502 of the act (21 U.S.C. 352) and are subject to seizure and other sanctions under the act.

FDA's regulations providing for insulin certification are set forth in part

429 (21 CFR part 429). These regulations include requirements for packaging and labeling (§§ 429.10 through 429.12), product standards (§§ 429.25 and 429.26), tests and methods of assay (§ 429.30), and the contents of requests for certification and samples required to be submitted (§ 429.40), as well as setting forth the standards for review and approval of requests for certifications (§ 429.41). In addition, insulin is considered to be a new drug subject to section 505 of the act (21 U.S.C. 355). Therefore, drug products containing insulin must have an approved new drug application, submitted and approved under section 505 of the act and 21 CFR part 314 of the regulations, to market the drug in interstate commerce.

Under FDA's insulin certification program, insulin manufacturers submit a "Request for Certification of an Insulin Batch" containing manufacturing and analytical data, as well as product samples of the master lot of insulin crystals and insulin finished dosage forms, to FDA's Division of Prescription Drug Compliance and Surveillance and FDA's insulin laboratory in the agency's Center for Drug Evaluation and Research. The Division of Prescription Drug Compliance and Surveillance reviews the incoming requests and determines which tests that FDA needs to perform. After review of the analytical data, physical examination, and completion of testing, FDA's insulin laboratory forwards its report and recommendation to the Division of Prescription Drug Compliance and Surveillance, where the data is reviewed and compared with the data reported in the manufacturer's request for certification. If both documents show that the batch conforms to the requisite standards of identity, strength, quality, and purity, the agency issues an insulin certificate.

II. Fee Schedule

Section 506(b)(5) of the act requires FDA to establish such fees as are necessary to provide, equip, and maintain an adequate certification service. These fees are intended to recover the full costs of operation of FDA's insulin certification program. The current fee schedule set forth in § 429.55(b) was published as an interim final rule in the Federal Register of October 4, 1991 (56 FR 50248). This interim final rule revises those fees to more accurately reflect the cost of maintaining the insulin certification program. FDA currently charges \$3,900 to certify each master lot and \$2,800 to certify each dosage form batch. Under the new fee schedule, FDA will charge

\$2,400 to certify each master lot and \$1,700 for each dosage form batch. All cost estimates are described in detail in a September 1995 FDA study of the insulin certification program's cost. A copy of the study has been placed on file at the Dockets Management Branch (address above). A provision of the current fee schedule allowing FDA to increase fees as Government salaries increase has been retained, with minor changes to emphasize the discretionary nature of any such fee increase. Fee increases based on salary increases will not take place before January 1, 1997.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

IV. Analysis of Impacts

FDA has examined the impacts of the interim final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this interim final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the interim final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA estimates that the fee schedule set out in this interim final rule will result in a decrease of approximately \$400,000 annually in fees collected by the agency, and will not result in any increase in cost to manufacturers of drug products containing insulin. The agency certifies that the interim final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.