DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92S–0251]

Electronic Submissions; Establishment of Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to provide information on submissions the agency is prepared to accept electronically. FDA is taking this action to provide easily accessible notice to the public when agency receiving units are prepared to accept electronic submissions and to promote the use of electronic technology.

ADDRESSES: The public docket is available under the docket number found in brackets in the heading of this notice and is located in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The public docket is also posted to the agency's Internet World Wide Web site at http://www.fda.gov

FOR FURTHER INFORMATION CONTACT: Paul J. Motise, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–1089, or e–mail address via Internet: Motise@CDER.FDA.GOV

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the Federal Register FDA is finalizing part 11 (21 CFR part 11) providing the conditions under which the agency will accept electronic signatures, electronic records, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed to paper. Part 11 applies to any required records submissions under the Federal Food, Drug, and Cosmetic Act (the act), the Public Health Service Act (the PHS Act), or Title 21 of the Code of Federal Regulations (CFR) and supersedes any paper record requirements by providing that electronic records may be used in lieu of paper records. Electronic signatures that meet the requirements of part 11 will be considered to be equivalent to full handwritten signatures, initials, and other general signings required by agency regulations. Part 11 also provides that, for records required to be maintained but not submitted to the agency, electronic records and accompanying signatures may be used in lieu of traditional records and signatures provided certain requirements are met.

Records and signatures submitted to the agency must satisfy the requirements of part 11 and must be identified in public docket number 92S–0251 as the type of submission the agency will accept in electronic form. The public docket will contain information pertaining to submissions for such agency units as the Centers for Drug Evaluation and Research, Biologics Evaluation and Research, Devices and Radiological Health, Food Safety and Applied Nutrition, Veterinary Medicine, and the Office of Regulatory Affairs. The information available will include a description of the document that may be submitted electronically; a citation, if any, to that section of the act, the PHS Act, or the CFR under which the document is submitted; the agency unit prepared to accept the document electronically (the receiving unit); and the address of the receiving unit. Unless records are identified in this public docket as acceptable for electronic submission, only paper records will be regarded as official submissions.

Several comments submitted to FDA on the proposed rule on electronic records and signatures (59 FR 45160, August 31, 1994) requested that the public docket provide more specific information and that submission procedures be uniform throughout the agency. FDA has decided not to include such uniform and specific requirements at this time because of the rapid advances in electronic technology, the variety of information required by different receiving units, and the number of different electronic systems used in the agency and regulated industry. Instead, FDA will maintain only basic information in the public docket because the agency expects that persons planning to submit a document will be in direct contact with the agency unit assigned to receive the submission. The receiving unit will provide details on the technical aspects of submissions such as media, method of transmission, file format, archiving needs, and technical protocols.

The agency will update the public docket periodically as FDA units acquire the ability to accept electronic submissions. Persons should, however, consult the appropriate receiving units directly to obtain the most current and detailed information on electronic submissions.

The public docket is available for public review in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 12, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

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