

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 1992S-0251] (formerly 92S-0251)

Food and Drug Administration Electronic Submissions Gateway

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the FDA Electronic Submissions Gateway (ESG) for the receipt and processing of electronic submissions provided so that the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) can receive regulatory submissions electronically. The FDA ESG enables applicants to send applications and other submissions for review using the Internet, provides a single point of entry for these submissions, and fulfills goals identified in the Prescription Drug User Fee Act (PDUFA III).

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SUPPLEMENTARY INFORMATION: FDA receives a variety of electronic submissions under 21 CFR 11.2(b), including biological license applications (BLAs), new drug applications (NDAs), drug master files (DMFs), investigational new drug

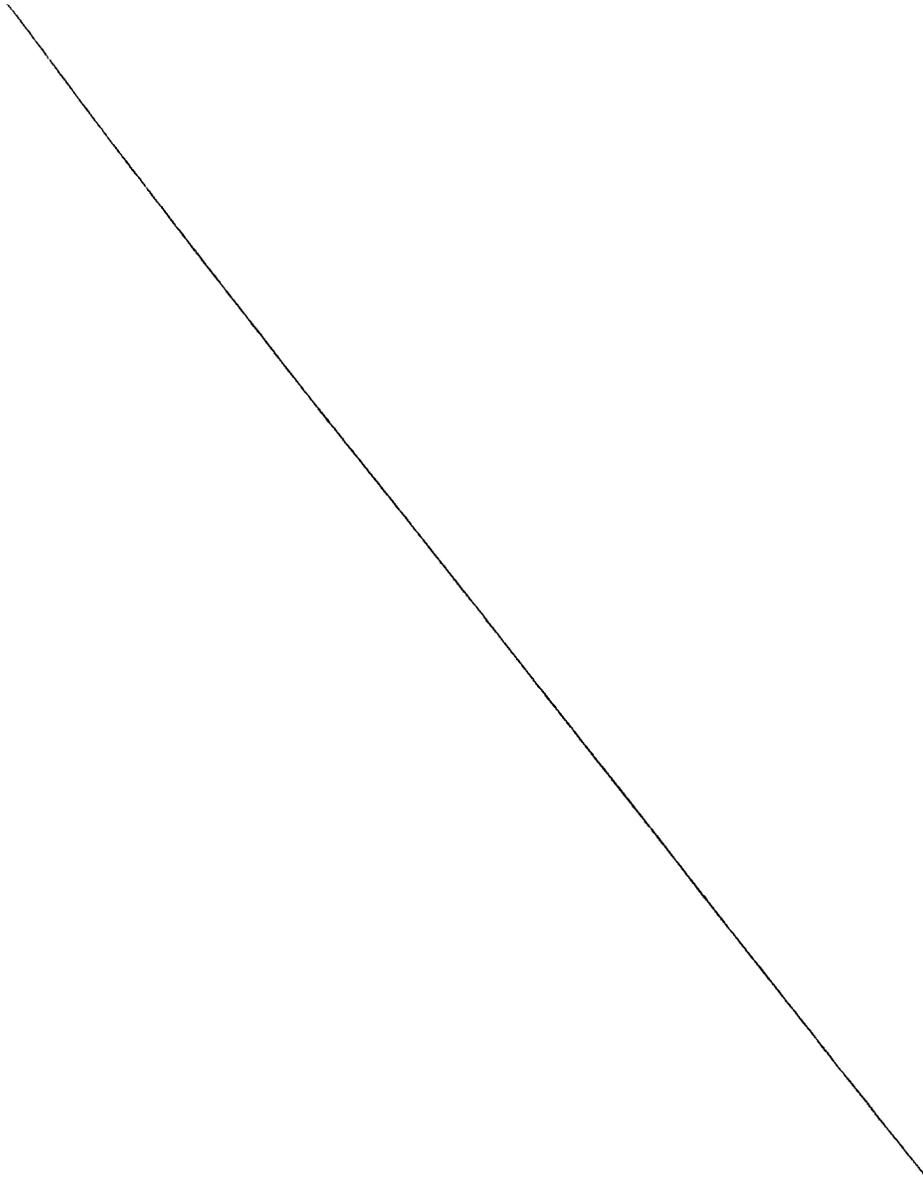
applications (INDs), and investigational device exemptions (IDEs), as well as their associated correspondence and other types of regulatory submissions. The FDA ESG supports the receipt and processing of electronic submissions through the use of a single point of entry.

The increasing number of electronic submissions highlights a critical need to automate and standardize the receipt of these submissions and their delivery to the appropriate centers. The FDA ESG automates the receipt, acknowledgment (to the applicant/sponsor), routing, and notification (to a receiving center) of electronic submissions via the Internet and meets the standards for the electronic exchange of information adopted by the American National Standards Institute (ANSI) and the National Institute of Standards and Technology (NIST).

The FDA ESG offers two secure communication options for applicants that have established gateway systems. One utilizes simple mail transfer protocol (SMTP) with secure multi-purpose internet mail extensions (S/MIME) to provide secure e-mail communication and the other supports faster information exchange and utilizes hypertext transfer protocol secure (HTTPS) to provide real-time Internet communication. The FDA ESG also offers a secure WebTrader submission option for applicants who do not have gateway systems. The WebTrader is a no-cost applet which can be downloaded from FDA and requires only a standard security certificate to provide the applicants with a secure Internet connection to FDA. The WebTrader addresses the need to expand participation in electronic submissions without costly expenditures for infrastructure upgrades and gateway systems.

Use of the FDA ESG is voluntary. Electronic format submissions may be made through the gateway or may continue to be made on physical media.

Information on the FDA ESG is available on the following Web site: <http://www.fda.gov/esg/>. Except where FDA has promulgated regulations requiring submission in electronic format, applicants/sponsors may also continue to make regulatory submissions on paper.



If you wish to use the FDA ESG, you should send an e-mail to *esgprep@fda.gov* to begin the registration process. Include your name, phone number, and the name of the company you represent. Please state whether you are using the WebTrader, SMTP, or HTTPS for submissions.

Dated: 8/1/06
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Jeffrey Shuren,
Assistant Commissioner for Policy.

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