DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0319]

Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection; Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled “Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection,” dated December 11, 1996. The guidance document, which discusses the appearance in 1996 of two cases of HIV–1 Group O infection in the United States, is intended to provide interim measures to reduce the risk of HIV–1 Group O transmission by blood and blood products pending the licensure of test kits specifically labeled for detection of antibodies to HIV–1 Group O viruses. As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. It is intended to provide recommendations and does not set forth requirements. In response to public comment, development of suitable alternatives or other new information, FDA may revise this guidance document at any time to improve its usefulness. Any revisions to this document will be announced in the Federal Register. The recommendations in the document represent the agency’s current thinking on deferral of donors at increased risk for HIV–1 Group O infection. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.


William K. Hubbard,
Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0381]

Guidance for Industry on Archiving Submissions in Electronic Format—NDA’s; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled “Archiving Submissions in Electronic Format—NDA’s.” This guidance is intended to describe how to submit records and other documents in electronic format to the Center for Drug Evaluation and Research (CDER) for archival purposes. Guidance is provided on submitting case report forms and case report tabulations as part of new drug applications (NDA’s). This is the first in a series of guidances for industry that will address archiving NDA submissions in electronic format. Guidance for industry on other submission types will be made available as they are completed. The submission of records in electronic format should reduce the amount of paperwork for applicants and the agency. Submissions in electronic format are voluntary.


William K. Hubbard,
Associate Commissioner for Policy Coordination.

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