

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D-1341]

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4-10-06
4-11-06
J. [unclear]

Draft Guidance for Industry: Center for Biologics and Evaluation Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance that was issued on July 11, 2001.

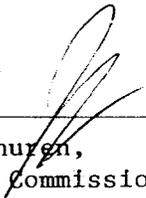
DATES: [*Insert date of publication in the Federal Register.*]

FOR FURTHER INFORMATION CONTACT: Pamela Pope, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

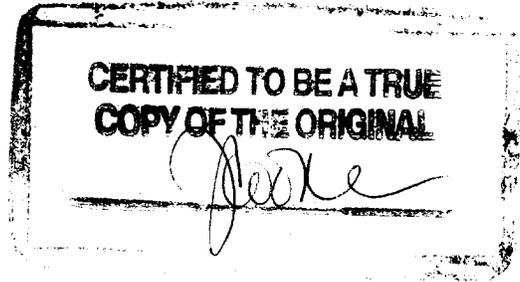
SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 11, 2001 (66 FR 36287), FDA announced the availability of a draft guidance entitled "Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier." This draft guidance described a pilot program in which biologics manufacturers could self-certify conformance to licensing criteria prescribed by FDA. This action was intended to reduce unnecessary burdens for industry without diminishing public health protection.

The draft guidance is being withdrawn because FDA has determined that there is a lack of industry interest in pursuing the pilot licensing program outlined in the draft guidance.

Dated: 3/31/06
March 31, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.



[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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