techniques and (2) appropriateness of various test methods for assessing blend uniformity. The agency has decided that further research on BUA is needed. FDA is participating in research on BUA through the Product Quality Research Institute (PQRI). Based on the results of the research and recommendations submitted by PQRI, FDA will determine whether a new guidance on BUA will be issued.

An applicant or manufacturer must still comply with any applicable regulations regardless of the status of this guidance. For example, an application must include specifications and analytical methods to ensure the identity, strength, quality, purity, and bioavailability of the drug product (21 CFR 314.50(d)(1)(ii)(a)), and a manufacturer must monitor and validate the performance of processes that could be responsible for variability, including adequacy of mixing to ensure uniformity and homogeneity (21 CFR 211.110(a)(3)). An evaluation of uniformity of a blend may be necessary to fulfill such requirements.

Dated: May 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12359 Filed 5–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1679]

Compliance Policy Guidance for FDA Staff and Industry on Blood Donor Classification Statement, Paid or Volunteer Donor; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Blood Donor Classification Statements, Paid or Volunteer Donor,'' dated May 7, 2002. The guidance document provides guidance to FDA staff and industry for determining when blood or blood components should be labeled with a ''paid donor'' or ''volunteer donor'' classification statement. The document is intended to assist industry in determining when a donor incentive is considered a monetary payment, and to assist FDA employees in inspecting blood centers. This guidance finalizes the document entitled ''Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives,'' published in the **Federal Register** of January 16, 2001 (66 FR 3605).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this compliance policy guidance to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your requests. You may fax your request to 301–827–0852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Tom M. Chin, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0410.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance policy guidance document entitled ''Blood Donor Classification Statements, Paid or Volunteer Donor,'' dated May 7, 2002. The guidance document provides information to industry and FDA employees regarding when a blood donor incentive would require the blood or blood component to be labeled with a ''paid donor'' or ''volunteer donor'' classification statement.

In the **Federal Register** of January 13, 1978 (43 FR 2142), FDA published a final rule requiring that blood and blood components intended for transfusion include a statement on the labels that indicated whether the products were collected from a paid or volunteer donor (§ 606.121(c)(5) (21 CFR 606.121(c)(5))). The regulation defines a ''paid donor'' as a person who receives monetary payment for blood donation (§ 606.121(c)(5)(i)). A volunteer donor is a person who does not receive monetary payment for blood donation (§ 606.121(c)(5)(ii)).

The requirement for a donor classification statement applies only to blood and blood components intended for transfusion. It does not apply to blood and blood components intended for further manufacturing, such as Source Plasma.

If the donor receives an incentive other than cash, the incentive must be evaluated to determine if it is readily convertible to cash. This guidance document provides FDA employees and industry with the factors that FDA uses to evaluate incentives, and provides some examples of incentives that the Center for Biologics Evaluation and Research has evaluated in the past.

This guidance finalizes the draft guidance entitled ''Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives'' (66 FR 3605). The title of the document was changed to more accurately reflect its contents.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on blood donor classification statements. 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 statutes and regulations.

III. Discussion of Comments

The agency received a number of comments on the draft compliance policy guidance (66 FR 3605). All of the comments were considered when preparing the final document.

Some of the comments requested further guidance on blood donor incentives that was outside of the scope of this document. FDA will consider issuing further guidance on the subject of blood donor incentives in the future.

IV. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ora/compliance__ref/cpg/default.htm.

Dated: May 7, 2002.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 02–12360 Filed 5–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0084]

Guidance for Industry on Special Protocol Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Special Protocol Assessment.'' This guidance provides guidance for industry on procedures adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to evaluate issues related to the adequacy (*e.g.*, design, conduct, analysis) of certain proposed studies.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, FAX 888–CBERFAX or 301–827–3844. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Kim M. Colangelo, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 9, 2000 (65 FR 6377), FDA announced the availability of a draft version of this guidance for industry entitled ''Special Protocol Assessment.'' The agency has finalized that draft guidance after considering comments received on the draft guidance version. Eight comments were received, and minor changes were made to the draft guidance version in an effort to make the document more clear.

Section 119(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105–115) amends section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and directs FDA to allow sponsors to request special protocol assessment and for the agency to act on such requests. Moreover, in conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 in November 1997, FDA agreed to specific performance goals for special protocol assessment and agreement. The performance goals are summarized in an enclosure to a letter dated November 12, 1997, from the then Secretary of Health and Human Services, Donna E. Shalala, to Senator James E. Jeffords.

The procedures and policies described in this guidance were adopted by CDER and CBER for evaluating issues related to the adequacy (*e.g.*, design, conduct, analysis) of proposed studies. These procedures will implement section 119(a) of the Modernization Act and are consistent with the timeframes described in the performance goals.

In the **Federal Register** document (65 FR 6377) announcing the availability of the draft version of this guidance, FDA published the proposed collection of information related to the draft guidance. The document also requested comments on the burden estimates for the draft guidance. In the **Federal Register** of May 29, 2001 (66 FR 29147), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance have been approved under OMB control number 0910–0470. This approval expires July 31, 2004. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This level 1 guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The guidance represents the agency's current thinking on special protocol assessment in CDER and CBER. 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 statutes and regulations. The guidance will be updated as appropriate.

II. Comments

Interested persons may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder.guidance/index.htm*, or *http://www.fda.gov/cber/guidelines.htm*.

Dated: May 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12327 Filed 5–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0388]

Draft Guidance for Industry on Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry entitled ''Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release, and