

products intended for use in the manufacture of blood and blood components or for the maintenance of data that personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion of further manufacture are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(h)]. This initiative was also described in a Federal Register (FR) notice dated August 31, 1994 (59 44991) [copy enclosed].

As a medical device manufacturer, you are currently required under the Act to register your establishment and list your devices. In addition, your manufacturing operations are required to be in compliance with CGMP for devices, and you must report adverse events and other problems as required by FDA's Medical Device Reporting (MDR) regulations. FDA's device registration and listing regulations appear at Title 21, *Code of Federal Regulations* (CFR), Part 807; CGMP regulations for devices appear at 21 CFR, Part 820; and the MDR regulations appear at 21 CFR, Part 803. These and other specific points relating to establishment inspections noted in the March 31, 1994, letter and the August 31, 1994, Federal Register notice remain unchanged.

In these documents, FDA stated that manufacturers of blood establishment computer software would be required to submit to the Center for Biologics Evaluation and Research (CBER) a premarket notification or application for premarket approval for each of their devices no later than March 31, 1995. The agency received numerous responses from organizations representing both software manufacturers and blood establishments. The principal concern expressed in these responses related to the requirements for premarket clearances or approval for blood establishment computer software products. The concerns included, but were not limited to, the difficulty of expeditious compliance with the requirement for premarket clearance or approval, the need for additional, detailed guidance to be used in the preparation of premarket submissions for these specific software products, and additional time needed to remove software from use by blood establishments in situations where a software manufacturer does not intend to seek premarket clearance or approval for the particular product.

After careful evaluation of the needs expressed by the software manufacturers and the impact of this regulatory initiative on blood establishments, the FDA has concluded that a one year extension of the March 31, 1995, deadline is warranted. Therefore, premarket submissions should be submitted to CBER no later than March 31, 1996. The extension period for premarket submissions does not, however, affect other responsibilities of the computer software manufacturers and distributors who are subject to the device provisions of the Act and implementing regulations as previously stated.

To effectively implement this important and complex regulatory program, the agency intends to work with industry to clarify the expectations concerning premarket submissions through issuance of guidance.

We also plan to have a continuing dialogue with affected establishments and industry organizations.

Also, within this extension period, it is the FDA's expectation that vendors and blood establishments will cooperatively conduct all transitions from software products for which premarket clearance or approval will not be sought to software products for which premarket clearance or approval is being actively pursued. These transitions should also be conducted in an orderly and effective manner so that they have minimal impact on the blood establishment's operations as they relate to the identity, safety, purity, and quality of blood products. These transitions should also be completed by March 31, 1996.

If you do not intend to make a premarket submission as outlined in the August 31, 1994, Federal Register notice, this information should be promptly sent to: Center for Biologics Evaluation and Research (CBER), Division of Blood Applications (HFM-370), 1401 Rockville Pike, Rockville, MD 20852-1448. The information should include your intent to remove software from the market and identify the steps to be taken and the support to be provided during the time needed for users to efficiently transition to other products or software manufacturers by March 31, 1996.

If you intend to make a premarket submission and have not done so by September 30, 1995, we request that you notify CBER by letter of the specific progress made by that point in time, the work remaining to be completed, and the anticipated date of filing each applicable premarket submission if not completed and submitted by September 30, 1995.

If you have questions concerning: (1) the preparation of the establishment registration and device listing notification, contact Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), at 301-443-6597, or (2) guidance for premarket submissions, contact Center for Biologics Evaluation and Research, Division of Blood Applications (HFM-370), at 301-594-2012. Please note that information regarding the content and format for premarket notification submission can be found at 21 CFR, Part 807, Subpart E.

Dated: September 26, 1995.  
William B. Schultz,  
*Deputy Commissioner for Policy.*  
[FR Doc. 95-24534 Filed 9-28-95; 11:22 am]  
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## Food And Drug Administration

[Docket No. 92N-0391]

### Analysis of Adverse Reactions to Monosodium Glutamate (MSG); Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of a document entitled "Analysis of Adverse Reactions to Monosodium Glutamate (MSG)," which the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) has prepared under a contract with FDA. As announced in the Federal Register of December 4, 1992, the agency requested that LSRO/FASEB undertake a reexamination of scientific data on possible adverse reactions to MSG.

**ADDRESSES:** "Analysis of Adverse Reactions to Monosodium Glutamate (MSG)" may be ordered from the Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814. The cost of a single paper copy is \$50. Payment may be made by check or money order. For telephone orders or further information on placing an order, call LSRO/FASEB at 301-530-7030.

**FOR FURTHER INFORMATION CONTACT:** Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3103.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of December 4, 1992 (57 FR 57467), FDA announced that it had requested that LSRO/FASEB undertake a reexamination of scientific data on possible adverse reactions to MSG, under a contract (223-92-2185) with FDA. The announcement also solicited data and information and advised that there would be an open meeting, which was held on April 7 and 8, 1993, for public oral presentation of scientific data, information, and views. LSRO/FASEB completed this review and submitted to FDA a final report entitled "Analysis of Adverse Reactions to Monosodium Glutamate (MSG)". The agency is now announcing the availability of this final report.

Dated: September 25, 1995.  
William B. Schultz,  
*Deputy Commissioner for Policy.*  
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## National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings: