Dated: April 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–9349 Filed 4–8–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0149]

Guidance for Industry on National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs; 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 ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs.'' This guidance is intended to clarify the administrative processes that will be followed in implementing the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Copies of this guidance for industry may be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the guidance entitled ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs.'' Section 412 of Title IV of FDAMA, signed into law by President Clinton on November 21, 1997, amended section 502(e)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(e)(1)) to add as a requirement that the established name and quantity or, if determined to be appropriate, the proportion of each active ingredient appear on the label of all over-the-counter (OTC) drug products intended for human use. FDAMA amended section 502(e)(1) of the act to require the listing of inactive ingredients on drug product labels, including the labels of OTC drug products intended for human use.

In addition, in the **Federal Register** of February 27, 1997 (62 FR 9024), FDA issued a proposed rule that would establish a standardized format for the labeling of OTC drug products. The rule, which is being finalized, is intended to make labeling for OTC drug products easier to read and understand. This guidance for industry advises manufacturers, packers, and distributors of the agency's current thinking on implementing these provisions of FDAMA, as they apply to OTC drug products, in coordination with the forthcoming finalization of the proposed OTC labeling rule.

This guidance 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.

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

Dated: March 12, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–9350 Filed 4–8–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2246–N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Continuance of Approval as an Accrediting Organization: the Joint Commission on Accreditation of Healthcare Organizations, the American Association of Blood Banks, and the American Osteopathic Association

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the continued approval of accrediting organizations for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program for the following organizations: The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Association of Blood Banks (AABB), and the American Osteopathic Association (AOA). This represents a continuation of the initial exemptions published in the **Federal Register** on—

- January 3, 1995 (60 FR 130)—JCAHO.
- July 21, 1995 (60 FR 37660)—AABB.
- July 21, 1995 (60 FR 37657)—AOA.

We have found that the accreditation process of these organizations provides reasonable assurance that the laboratories accredited by them meet the conditions required by Federal law and regulations. Consequently, laboratories that voluntarily become accredited by one or more of these organizations (as applicable) and continue to meet the organization's requirements would meet the CLIA condition level requirements for laboratories. Therefore, laboratories accredited by one or more of these organizations (as applicable) are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective on April 9, 1998 through June 30, 1999 for the JCAHO, and July 21, 2001 for the AABB and the AOA.

FOR FURTHER INFORMATION CONTACT:
Joan Simmons, (410) 786–3408 (JCAHO)
Virginia Wanamaker, (410) 786–3384 (AABB)
Kathleen Todd, (410) 786–3385 (AOA)