Dated: April 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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)

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act (PHSA), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory that performs tests on human specimens to meet requirements established by the Department of Health and Human Services (HHS). Under the provisions of sections 1861(s)(14) and (s)(16) of the Social Security Act, any laboratory that also wants to be paid for services furnished to Medicare beneficiaries must meet the requirements of section 353 of the PHSA. Subject to specified exceptions, laboratories must have a current and valid CLIA certificate to test human specimens or be eligible for payment from the Medicare or Medicaid programs. Regulations implementing section 353 of the PHSA are contained in 42 CFR part 493. Section 353(e)(2) of the PHSA permits HCFA to approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to, or more stringent than, the applicable CLIA program requirements established at 42 CFR part 493.

Section 493.501 allows us to deem a laboratory to meet the CLIA requirements if the accreditation process of the organization requesting approval provides reasonable assurance that the laboratories accredited by it meet the conditions required by Federal law and regulations, including the requirements at § 493.506. Under § 493.501, the accreditation organization must also—

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HHS;
- Apply standards and criteria that are equal to, or more stringent than, those condition level requirements established by HHS; and
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories.

A laboratory can be accredited if it meets the standards of an approved accreditation body and meets the requirements at § 493.501(b).

II. Requirements for Granting CLIA Approval

In order to determine whether we should grant or continue an existing CLIA approval to laboratories accredited by a private accrediting organization, we conduct a detailed and in-depth comparison between the organization's requirements and the CLIA requirements at § 493.501 to determine whether the organization meets the CLIA requirements.

As specified at § 493.506, our review of an accrediting organization's laboratory program includes (but is not necessarily limited to) an evaluation of the following:

- Whether the organization's requirements for laboratories are equivalent to, or more stringent than, the CLIA condition level requirements.
- The organization's inspection process requirements to determine the following:
  + The comparability of the full inspection and complaint inspection procedures to those of HCFA;
  + The ability of the organization to provide us with electronic data and reports with the adverse or corrective actions resulting from proficiency testing (PT) results that constitute unsuccessful participation in HCFA-approved PT programs and with other data we determine to be necessary for validation and assessment of the organization's inspection process requirements.
- The organization's agreement with us to ensure that the organization agrees to do the following:
  + Notify us within 30 days of all newly accredited laboratories, including the specialties and subspecialties for which any laboratory performs testing.
  + Notify us within 30 days of the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked.
  + Notify us within 10 days of any deficiency identified in an accredited laboratory when the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.
  + Notify us at least 30 days prior to changing its standards.
  + Notify each laboratory accredited by the organization within 10 days of our withdrawal of approval.
  + Disclose any laboratory's PT results upon the reasonable request by any person.
  + Provide us, as requested, with inspection schedules for validation purposes.

Under § 493.501(d), the approval period may not exceed 6 years. Section 493.501(e) provides that we publish a notice in the **Federal Register** announcing the names of accrediting organizations whose laboratories are deemed as meeting requirements equivalent to those of part 493. This notice must describe the basis for granting deeming authority to the accreditation organization. In addition, the notice must describe how the accreditation organization provides reasonable assurance to us that laboratories accredited by it meet CLIA requirements equivalent to those specified in part 493 and would, therefore, meet the CLIA requirements if, rather than being granted deemed status, they had been inspected against CLIA condition level requirements.

We published notices in the **Federal Register** announcing that the JCAHO (January 3, 1995; 60 FR 130), the AABB July 21, 1995; 60 FR 37660) and the AOA (July 21, 1995; 60 FR 37657) had applied for approval of their accreditation program for laboratories under the CLIA program; that the evaluation of these organizations' applications demonstrated that all requirements for approval were met; and that these organizations were granted approval as accreditation organizations under CLIA.

III. Evaluation of Requests for Continued CLIA Approval

The JCAHO, the AABB, and the AOA applied to us for continued approval of their laboratory accreditation programs under CLIA. As with the initial application, we evaluated the requests for continuation of these organizations' approvals for equivalency against the three major categories of CLIA rules: The implementing regulations, the enforcement regulations, and the deeming/exemption requirements.

We evaluated the applications to verify these organizations' assurances of continued compliance with the following subparts of part 493: Subpart H, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (including the Subcategory), High Complexity, or any Combination of These Tests; Subpart J, Patient Test Management For Moderate Complexity (including the Subcategory), High Complexity, or any Combination of These Tests; Subpart K, Quality Control for Tests of Moderate Complexity (including the Subcategory), High Complexity, or any Combination of These Tests; Subpart M, Personnel for Moderate Complexity (including the Subcategory) and High Complexity Testing; Subpart P, Quality Assurance for Moderate Complexity (including the Subcategory), or High Complexity Testing, or any Combination of These Tests; Subpart Q, Inspection; and Subpart R, Enforcement Procedures.

These organizations continue to meet the requirements of subparts H, J, K, M, P, Q, and R as they were described in

the January 3, 1995 and July 21, 1995 **Federal Register** notices.

IV. Federal Validation Inspections and Continuing Oversight

Federal validation inspections and continuing oversight of these accredited laboratories are conducted based on §§ 493.507 and 493.509; that is, they are conducted on a representative sample basis as well as in response to substantial allegations of noncompliance (complaint inspections). We have conducted Federal validation inspections of a sample of these accredited laboratories, as specified in § 493.507, and evaluated the findings. The evaluations confirmed the satisfactory performance of these organizations as accrediting organizations for clinical laboratories under the CLIA program. These organizations are maintaining their workloads at the proper level to ensure that all laboratories using one or more of these laboratory accreditation programs (as applicable) to meet CLIA requirements will be inspected in a 24-month cycle. All parameters monitored by HCFA staff to date indicate that these organizations are meeting all requirements under the CLIA approvals. This Federal monitoring process will continue as an ongoing process.

The CLIA approval of laboratories accredited by these organizations may be removed if we determine the outcome and comparability reviews of validation inspections are not acceptable as described under § 493.511.

V. Approval as an Accrediting Organization

HCFA grants continuation of the CLIA approval for all specialties and subspecialties for which the JCAHO, the AABB, and the AOA were previously approved (as noted below) to all laboratories accredited by and using one or more of these organizations' laboratory accreditation programs (as applicable) to meet CLIA requirements. The CLIA approval for these organizations continues until the following dates and for the following areas:

- JCAHO—June 30, 1999; all specialties and subspecialties.
- AABB—July 21, 2001; limited to the Immunohematology, Diagnostic Immunology, Hematology, Histocompatibility, Routine Chemistry, and Toxicology.
- AOA—July 21, 2001; all specialties and subspecialties.

VI. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a notice such as this would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all laboratories to be small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such analysis must conform to the provisions of sections 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than fifty beds.

This notice announces the continuance of the approvals of laboratories accredited by one or more of these organizations' accreditation programs as meeting the CLIA requirements. These organizations have established that their standards in determining whether or not to accredit a laboratory are equal to, or more stringent than, those of the CLIA program, and also have established that they have a comparable program to monitor and evaluate compliance with the standards. The effect of the continued approval of these organizations' accreditation programs as meeting the CLIA requirements is that laboratories will continue to be allowed to use these respective accreditation programs to meet the requirements of CLIA with no discernable difference in the operations of the program. Consequently, we anticipate that our continuation of these organizations' CLIA approval will not affect the laboratories or the quality and availability of services furnished.

We have determined, and the Secretary certifies, that this notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or sections 1102(b) of the Act.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Sec. 353(e)(2) of the Public Health Service Act (42 U.S.C. 263a).

Dated: February 17, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–9263 Filed 4–8–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: March 1998

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of March 1998, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
Program-Related Convictions	
Bigelsen, Harvey, San Diego, Ca	04/20/1998
Blackwell, Robert Earl, Little Rock, AR	04/20/1998
Burton, Richard James, Little Rock, AR	04/20/1998
Daw, Michael Edward, Goodyear, AZ	04/20/1998
Fontaine, Barbara, Culver City, CA	04/20/1998