

of employment under the grant, the employee will:

(1) Abide by the terms of the statement; and, (2) Notify the employer in writing of his or her conviction for a violation or a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, of every grant officer or other designee on whose grant activity the convicted employee was working unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or, (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant (Use attachments, if needed):

Place of Performance (Street address, City, County, State, ZIP Code) _____
Check _____ if there are workplaces on file that are not identified here.

Sections 76.630 (c) and (d)(2) and 76.635 (a)(1) and (b) provide that a Federal agency may designate a central receipt point for STATE-WIDE AND STATE AGENCY-WIDE certifications, and for notification of criminal drug convictions. For the Department of Health and Human Services, the central receipt point is: Division of Grants Management and Oversight, Office of Management and Acquisition, Department of Health and Human Services, Room 517-D, 200 Independence Avenue, SW., Washington, DC 20201.

Signature _____
Date _____
Title _____
Organization _____

DGMO Form #2 Revised May 1990

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

By signing and submitting this proposal, the applicant, defined as the primary participant in accordance with 45 CFR Part 76, certifies to the best of its knowledge and belief that its principals involved:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department of agency;

(b) have not within a 3-year period preceding this proposal been convicted of or had a civil judgement rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery falsification or destruction of records, making false statements, or receiving stolen property;

(c) are not presently indicted or otherwise criminally or civilly charged by a government entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1) (b) of this certification; and

(d) have not within a 3-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

The inability of a person to provide the certification required above will not necessarily result in denial of participation for this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the Department of Health and Human Services' (HHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

The prospective primary participant agrees that by submitting this proposal, it will include the clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions", provided below, without modification in all lower tier covered transactions and in all solicitations for lower tier covered actions.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusions—Lower Tier Covered Transactions (To Be Supplied to lower Tier Participants)

By signing and submitting this lower tier proposal, the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(b) Where the prospective lower tier participant is unable to certify to any of the above, such prospective participants shall attach an explanation to this proposal.

The prospective lower tier participant further agrees by submitting this proposal that it will include this clause entitled "Certification Regarding Debarment, suspension, Ineligibility and Voluntary Exclusions—Lower Tier Covered

Transactions" without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Signature _____
Date _____
Title _____
Organization _____

Certification Regarding Lobbying

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan or cooperative agreement, the undersigned shall complete and submit Standard Form—LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all recipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Organization _____
Authorized Signature Title Date

Note: If Disclosure Forms are required, please contact: Mr. William Sexton, Deputy Director, Grants and Contracts Management Division, room 341F, HHH Building, 200 Independence Avenue, SW, Washington, D.C. 20201-0001.

[FR Doc. 95-22054 Filed 9-5-95; 8:45 am]

BILLING CODE 4130-01-M

Food and Drug Administration

[Docket No. 95M-0240]

Wesley-Jessen; Premarket Approval of Wesley-Jessen® COE-405 Disinfection Tablet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Wesley-Jessen, Des Plaines, IL, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Wesley-Jessen® COE-405 Disinfection Tablet. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on June 7, 1995, of the approval of the application.

DATES: Petitions for administrative review by October 6, 1995.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1744.

SUPPLEMENTARY INFORMATION: On February 13, 1991, Wesley-Jessen, Des Plaines, IL 60018, submitted to CDRH an application for premarket approval of Wesley-Jessen® COE-405 Disinfection Tablet. When the Wesley-Jessen® COE-405 Disinfection Tablet is dissolved in a sterile contact lens saline solution, the solution is indicated for use in the chemical (not heat) disinfection of soft (hydrophilic) contact lenses.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On June 7, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH

based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before October 6, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 24, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95-21973 Filed 9-5-95; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

[BPO-133-PN]

Medicare Program; Data, Standards, and Methodology Used to Establish Fiscal Year 1996 Budgets for Fiscal Intermediaries and Carriers

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

ACTION: Proposed notice.

SUMMARY: This notice describes the data, standards, and methodology that would be used to establish fiscal intermediary and carrier budgets for the Federal fiscal year (FY) 1996, that begins October 1, 1995. Fiscal intermediaries and carriers are public or private entities that participate in the administration of the Medicare program by performing claims processing and benefit payment functions. This notice is published in accordance with sections 1816(c)(1) and 1842(c)(1) of the Social Security Act, which require us to publish for public comment the data, standards, and methodology we intend to use to establish budgets for Medicare fiscal intermediaries and carriers.

In addition, we respond to the single public comment we received in response to our proposed notice of October 21, 1994, and we announce the data, standards, and methodology we proposed to use to establish the Medicare fiscal intermediary and carrier budgets for FY 1995, beginning October 1, 1994, as final.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 6, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPO-133-PN, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments (1 original and 3 copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPO-133-PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document,