

provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance 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.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: December 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-32789 Filed 12-17-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-1557]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Survey Report Form Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1-493.2001; Form No.: HCFA-1557 (OMB# 0938-0544); *Use:* CLIA requires the Department of Health and Human Services (DHHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by DHHS. The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. In order for the State survey agency to report to HCFA its findings on facility compliance with the individual standards on which HCFA determines compliance, the surveyor completes the Survey Report Form. The Survey Worksheet provides space to document the surveyor's notes.; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 30,512; *Total Annual Responses:* 15,526; *Total Annual Hours:* 7,628.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 10, 1999.

John Parmigiani,

Manager, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-3024-NC]

RIN 0938-AH15

Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

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

ACTION: Notice with comment period.

SUMMARY: This notice announces the requests we have received from entities seeking review of the appropriateness of the Medicare payment amount for new technology intraocular lenses furnished by Ambulatory Surgical Centers (ASCs). Interested parties submitted these requests under the provisions of a final rule published June 16, 1999. This rule detailed the process for requesting a review of these lenses.

DATES: We will consider comments regarding the lenses listed in this notice if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 19, 2000.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services (HHS), Attention: HCFA-3024-NC, P.O. Box 8017, Baltimore, MD 21244-8017.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201, or 7500 Security Boulevard, Baltimore, Maryland 21244.

Because of the staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-3024-NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's office at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT: Claude Mone, (410) 786-5666.

SUPPLEMENTARY INFORMATION: The following application requests have been submitted timely to the Health Care Financing Administration for review:

1. *Manufacturer:* Alcon Laboratories
Model Numbers: Acrysof Models MA30BA and MA60BM

Reason for Requesting Review: The manufacturer states that these lenses provide a reduction in the following:
—The rate of Nd:YAG capsulotomy.
—Posterior capsule opacification (PCO) by reduction in lens epithelial cells (LECs).

2. *Manufacturer:* Allergan
Model Numbers: AMO Silicone Posterior Chamber with UV Absorber Models SI40NB and SI55NB

Reason for Requesting Review: The manufacturer states that all of the following are significantly lower after 2 years of using these lenses:
—Visual acuity loss from best postoperative acuity.
—Incidence of Nd:YAG capsulotomy.
—Posterior capsule opacification (PCO) value.

3. *Manufacturer:* Allergan
Model Number: AMO Array Multifocal Model SA40N

Reason for Requesting Review: The manufacturer states that this lens demonstrates all of the following when compared to a monofocal lens:

—Improved near visual acuity.
—Increased depth of focus.
—Reduced spectacle usage for bilaterally implanted patients.

4. *Manufacturer:* Mentor Corporation (Acquired by CIBA Vision Corporation on July 1, 1999)

Model Numbers: MemoryLens Model Numbers U940A and U940S

Reason for Requesting Review: The manufacturer states that these lenses are the only small incision pre-rolled hydrophilic acrylic lenses in today's global market. The manufacturer did not identify any specific clinical advantages.

5. *Manufacturer:* Pharmacia & Upjohn Company

Model Numbers: CeeOn Heparin Surface Modified (HSM) Models 720C, 722C, 726C, 727C, 730C, 734C, 777C, 809C through 815C, and 820C

Reason for Requesting Review: The manufacturer states that the amount of cellular deposits and the number of giant cells are reduced with their HSM lenses when compared to non-HSM lenses.

6. *Manufacturer:* STAAR Surgical Company

Model Numbers: Elastic Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens with Toric Optic Models AA4203T, AA4203TF, and AA4203TL

Reason for Requesting Review: The manufacturer states that these lenses have the following advantages when compared to spherical (only) lenses:

—Improved uncorrected visual acuity.
—Decreased refractive cylinder resulting from corneal astigmatism.

Authority: Sections 1832 (a)(2)(F)(i) and 1833(i)(2)(A) of the Social Security Act (42 U.S.C. 1395k(a)(2)(F)(i) and 1395l(i)(2)(A)) (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 13, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99-32791 Filed 12-17-99; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Draft Environmental Impact Statement for the Proposed Cortina Integrated Waste Management Project, Colusa County, CA

AGENCY: Bureau of Indian Affairs, Interior

ACTION: Notice

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA) intends to submit a Draft Environmental Impact Statement (DEIS) for a proposed lease of approximately 443 acres held in trust by the federal government for the Cortina Band of Wintun Indians in Colusa County, California, to the Environmental Protection Agency for public review and comment. The purpose of the proposed action is to allow Cortina Integrated Waste Management, Inc., to develop and operate needed waste treatment facilities referred to as the Cortina Integrated Waste Management Project. The BIA prepared the DEIS in cooperation with the Cortina Band of Wintun Indians and the Band's environmental consultants. A description of the proposed project location and of the environmental issues addressed in the DEIS follow as supplementary information. This notice also announces a public hearing to receive public comments on the DEIS.

DATES: Written comments must arrive by February 15, 2000. The Public hearing will be held on February 2, 2000, from 6:30 p.m. to 9:00 p.m.

ADDRESSES: If you wish to comment, you may submit your comments by any one of several methods. You may mail or hand carry written comments to Ronald M. Jaeger, Regional Director, Pacific Region, Bureau of Indian Affairs,

2800 Cottage Way, Sacramento, California, 95825-1846. You may also comment via the Internet to billallan@bia.gov. Please submit Internet comments as an ASCII file, avoiding the use of special characters and any form of encryption. Include your name, return address and the caption, "DEIS Comments, Cortina Integrated Waste Management Project, Cortina Indian Rancheria of Wintun Indians, Colusa County, California," on the first page of your written comments or Internet message. If you do not receive confirmation from the system that your Internet message was received, contact us directly at (916) 978-6043.

Comments, including names and home addresses of respondents, will be available for public review at the above address during regular business hours, 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays. Individual respondents may request confidentiality. If you wish to withhold your name and/or address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. We will not, however, consider anonymous comments. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

To obtain a copy of the DEIS, please write or call William Allan, Environmental Protection Specialist, Pacific Region, Bureau of Indian Affairs, 2800 Cottage Way, Sacramento, CA 95825-1846, telephone (916) 978-6043.

The public hearing will be held at Colusa Industrial Properties, 100 Sunrise Boulevard, Colusa, California. This hearing will be co-hosted by the BIA and the Cortina Band of Wintun Indians.

FOR FURTHER INFORMATION CONTACT: William Allan, (916) 978-6043.

SUPPLEMENTARY INFORMATION: The proposed action is the approval of a 25 year lease of 443 acres of the 640 acre Cortina Rancheria to Cortina Integrated Waste Management, Inc., for the development and operation of a landfill, a materials recovery facility, a composting facility, a bio-remediation facility, plus ancillary facilities. These would occupy approximately 213 acres of the lease area. The proposed project site is located in the rugged eastern foothills of the Coast Ranges, just above the west side of the Sacramento Valley in northern California. It is