ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Plan	27	1	160	4,320
Estimated Total Annual Burden Hours	.....	.....	.....	4,320

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 17, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 96–18558 Filed 7–22–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96M–0216]

Biomira Diagnostics, Inc.; Premarket Approval of TRUQUANT® BR™ RIA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Thomas Tsakeris, Devices and Diagnostics Consulting Group, Rockville, MD, U.S. Representative for Biomira Diagnostics Inc., 30 Meridian Rd., Rexdale, ON, Canada, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of TRUQUANT® BR™ RIA. After reviewing the recommendation of the Immunology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 29, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 22, 1996.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On February 24, 1995, Thomas M. Tsakeris, Devices and Diagnostics Consulting Group, Rockville, MD, U.S. Representative for Biomira Diagnostics, Inc., Rexdale, ON, Canada, submitted to CDRH an application for premarket approval of TRUQUANT® BR™ RIA. The device is an in vitro diagnostic device indicated for quantitative determination of CA 27.29 antigen in serum or EDTA plasma of patients previously treated for Stage II or Stage III breast cancer. Serial testing for CA 27.29 antigen with TRUQUANT® BR™ RIA in patients who are clinically free of disease should be used in conjunction with other clinical methods used for the early detection of recurrence.

On September 21, 1995, the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On March 29, 1996, 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 the 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 August 22, 1996, 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: June 21, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–18556 Filed 7–22–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–849–PN]

Medicare Program; Recognition of the Ambulatory Surgical Center Standards of the Joint Commission on the Accreditation of Healthcare Organizations and the Accreditation Association for Ambulatory Health Care

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

ACTION: Proposed notice.

SUMMARY: This notice proposes to grant deeming authority to two organizations, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the Accreditation Association for Ambulatory Health Care (AAAHC), for their member ambulatory surgical centers (ASCs) that request Medicare certification. We believe that accreditation of ASCs by both organizations would demonstrate that all Medicare ASC conditions are met or exceeded, and, thus, we would grant deeming authority to each organization.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 22, 1996.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–849–PN, P.O. Box 7519, Baltimore, MD 21207–0519.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 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 BPD–849–PN. 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 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone (202) 690–7890).

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

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FOR FURTHER INFORMATION CONTACT: Bob Cereghino, (410) 786–4645.

SUPPLEMENTARY INFORMATION:

I. Background

A. Determining Compliance of Ambulatory Surgical Centers—Surveys and Deeming

In order to participate in the Medicare program, ambulatory surgical centers (ASCs) must meet conditions for coverage specified in regulations that implement title XVIII of the Social Security Act (the Act). ASCs enter into a Medicare participation agreement but generally only after they are certified by a State survey agency as complying with the ASC conditions for coverage set forth in the Act and regulations. ASCs are subject to regular surveys by State agencies to determine whether they continue to meet these requirements; an ASC that does not meet these requirements is considered out of compliance and risks having its participation in the Medicare program terminated.

Section 1865 of the Act includes a provision that permits ASCs to be exempt from routine surveys by the State survey agencies to determine compliance with the Medicare conditions for coverage. (Under our regulations at 42 CFR 416.40 (''Condition for coverage—Compliance with State licensure law''), an ASC must still meet the State's licensure requirements, however.) Specifically, section 1865(b) of the Act provides that if we find that accreditation of a provider entity by a national accreditation body demonstrates that all Medicare conditions or requirements are met or exceeded, we would (for certain providers, including ASCs) ''deem'' these entities as meeting the applicable Medicare conditions.

In making our finding as to whether the accreditation body makes this demonstration, we consider factors such as the accrediting body's accreditation requirements, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found to be out of compliance with the conditions or requirements, and its ability to provide us with necessary data for validation. If we find that the accreditation of an ASC by the national accreditation body demonstrates that the Medicare conditions imposed on ASCs are met, we would treat the accredited ASCs as meeting those conditions. ASCs as suppliers are included by definition of provider entity in section 1865(b)(4) of the Act. Thus, if we were to recognize an ASC