9. The response time with respect to the provision of services to families and children where an allegation of child abuse or neglect has been made.
10. For child protective service personnel responsible for intake, screening, assessment, and investigation of child abuse and neglect reports in the State—
   A. information on the education, qualifications, and training requirements established by the State for child protective service professionals, including for entry and advancement in the profession, including advancement to supervisory positions;
   B. data of the education, qualifications, and training of such personnel;
   C. demographic information of the child protective service personnel; and
   D. information on caseload or workload requirements for such personnel, including requirements for average number and maximum number of cases per child protective service worker and supervisor.
11. The number of children reunited with their families or receiving family preservation services that, within five years, result in subsequent substantiated reports of child abuse or neglect, including the death of the child.
12. The number of children for whom individuals were appointed by the court to represent the best interests of such children and the average number of out of court contacts between such individuals and children.
13. The annual report containing the summary of activities of the citizen review panels of the State required by subsection (c)(6).
14. The number of children under the care of the State child protection system who are transferred into the custody of the State juvenile justice system.
15. The number of children referred to a child protective services system under subsection (b)(2)(B)(ii).
16. The number of children determined to be eligible for referral, and the number of children referred, under subsection (b)(2)(B)(xxi), to agencies providing early intervention services under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*).

The Children's Bureau proposes to continue collecting the NCANDS data through the two files of the Detailed Case Data Component, the Child File (the case-level component of NCANDS) and the Agency File (additional aggregate data, which cannot be collected at the case level). Technical assistance will be provided so that all States may provide the Child File and Agency File data to NCANDS.

There are no proposed changes to the NCANDS data collection instruments. New fields were implemented during the previous OMB clearance cycle in support of the CAPTA Reauthorization Act of 2010 and to improve reporting on federal performance measures.

Respondents: State governments, the District of Columbia, and the Commonwealth of Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Detailed Case Data Component Child File and Agency File	52	1	82	4,264

Estimated Total Annual Burden Hours: 4,264.

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 may be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* 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) 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–00081 Filed 1–13–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1951]

CHEMBIOMED, LTD., Opportunity for a Hearing on a Proposal To Revoke U.S. License No. 0916

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the biologics license (U.S. License No. 0916) issued to CHEMBIOMED, LTD. (CHEMBIOMED), for the manufacture of Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal), Anti-Le[a] (Murine Monoclonal) and Anti-Le[b] (Murine Monoclonal). The proposed revocation is based on information that the firm is no longer in operation and the manufacture of its licensed products has been discontinued.

DATES: CHEMBIOMED may submit electronic or written requests for a hearing by February 13, 2015, and any data and information justifying a hearing by March 16, 2015. Other interested persons may submit electronic or written comments on the proposed revocation by March 16, 2015.

ADDRESSES: Submit electronic requests for a hearing, any data and information justifying a hearing, and comments to *http://www.regulations.gov.* Submit written requests for a hearing, any data and information justifying a hearing,

and any written comments on the proposed revocation to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John Reilly, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is initiating proceedings to revoke the biologics license (U.S. License No. 0916) issued to CHEMBIOMED, 9515 107th St., Rm. 401, Edmonton AB T5K 2C3, Canada, for the manufacture of Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal), Anti-Le[a] (Murine Monoclonal) and Anti-Le[b] (Murine Monoclonal). Proceedings to revoke U.S. License No. 0916 are being initiated under 21 Code of Federal Regulations (CFR) 601.5(b) because FDA has determined through various means that a meaningful inspection of CHEMBIOMED cannot be conducted because the manufacturer is no longer in operation. In addition, Health Canada has advised FDA that CHEMBIOMED is no longer in operation. According to the Industry Canada Web site (*www.ic.gc.ca*), CHEMBIOMED (Corporation No. 0228176 and Business No. (BN) 100938521RC0001 under the governing legislation of the Canada Business Corporations Act) was issued a Certificate of Incorporation on August 15, 1977, and later was issued a Certificate of Dissolution on March 17, 1999.

In a phone conversation that occurred on July 7, 1992, a former CHEMBIOMED employee informed FDA that CHEMBIOMED was no longer in business, had ceased the manufacture of licensed products, and had also ceased shipments of licensed products to the United States.

In a letter dated June 16, 1995, FDA requested from the Authorized Official (Responsible Head) of CHEMBIOMED a status update for the production of all of the products for which CHEMBIOMED held a U.S. license. This letter requested that the firm notify FDA in writing of the firm's status and also informed the Authorized Official that in the absence of a response to this letter that FDA would take action to revoke CHEMBIOMED's U.S. license. FDA did not receive a response to its letter dated June 16, 1995.

In a certified, return-receipt letter dated October 18, 1995, FDA requested that the Authorized Official of CHEMBIOMED inform FDA whether or not the firm intended to pursue a product license application supplement request dated May 6, 1987. In the October 18, 1995 letter, FDA also informed the Authorized Official that the product license application supplement request had been placed in the FDA inactive files. FDA did not receive a response to its certified, return-receipt letter dated October 18, 1995.

In a letter to CHEMBIOMED dated December 19, 2012, FDA provided notice of FDA's intent to revoke U.S. License No. 0916 and announced its intent to offer an opportunity for a hearing. FDA indicated that FDA registrations for CHEMBIOMED facilities have not been updated since May 12, 1994. The letter also advised the Authorized Official that, under 21 CFR 601.5(b)(1)(i) and (ii) of FDA's regulations, proceedings for license revocation may be instituted when FDA finds that authorized FDA employees have been unable to gain access to an establishment for the purpose of carrying out an inspection, or when the manufacturing of a product has been discontinued to an extent that a meaningful inspection cannot be made. The December 19, 2012 letter to CHEMBIOMED, sent via United Parcel Service (UPS), was returned as undeliverable.

II. Notice of Opportunity for Hearing

Because FDA has made reasonable efforts to notify CHEMBIOMED of the proposed revocation and no response has been received from the firm, FDA is proceeding under 21 CFR 12.21(b) and issuing this notice of opportunity for a hearing on a proposal to revoke the biologics license (US. License No. 0916) issued to CHEMBIOMED for the manufacture of Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal), Anti-Le[a] (Murine Monoclonal) and Anti-Le[b] (Murine Monoclonal).

FDA has placed copies of the documents relevant to the proposed revocation on file with the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) A phone conversation record dated July 7, 1992 between FDA and a former CHEMBIOMED employee; (2) an FDA letter to the Authorized Official of CHEMBIOMED dated June 16, 1995; (3) a certified, return-receipt letter from FDA to the Authorized Official of CHEMBIOMED dated October 18, 1995; (4) a UPS Express Mail, signature required letter from FDA to the Authorized Official of CHEMBIOMED, dated December 19, 2012, and returned as undeliverable; and (5) Industry Canada information that documents CHEMBIOMED, Corporation No. 0228176 and BN 100938521RC0001 under the governing legislation of the Canada Business Corporations Act, was issued a Certificate of Incorporation on August 15, 1977, and later was issued a Certificate of Dissolution on March 17, 1999. These documents are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

CHEMBIOMED may submit an electronic or written request for a hearing to the Division of Dockets Management by February 13, 2015, and any data and information justifying a hearing to the Division of Dockets Management by March 16, 2015. Other interested persons may submit electronic or written comments on the proposed license revocation to the Division of Dockets Management by March 16, 2015. The failure of the licensee, CHEMBIOMED, to file a timely electronic or written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation (§ 12.22(b)).

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on a proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest on mere allegations or denials, but must set forth a genuine and substantial issue of fact that requires a hearing (§ 12.24(b)). If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, the Commissioner of Food and Drugs (the Commissioner) will deny the hearing request, making findings and conclusions that justify the denial (§ 12.24(b)(3)).

Only one copy of any submission need be provided to FDA. Submissions are to be identified with the docket number found in brackets in the heading of this document. Such submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be examined in the Division of Dockets

Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at *http://www.regulations.gov.*

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Acts (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to the Commissioner and redelegated to the Director and Deputy Director of the Center for Biologics Evaluation and Research (FDA Staff Manual Guide 1410.203).

Dated: January 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00442 Filed 1–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Determining Mental Health Professional Shortage Areas of Greatest Need

AGENCY: Health Resources and Services Administration (HRSA), Health and Human Services (HHS).

ACTION: updating of the scoring criteria for determining mental health professional shortage areas (HPSA) of greatest need.

SUMMARY: In accordance with the requirements of section 333A(b)(1) of the Public Health Service (PHS) Act, as amended by the Health Care Safety Net Amendments of 2002, 42 U.S.C. 254f-1(b)(1), the Secretary of HHS shall establish the criteria which she will use to make determinations under section 333A(a)(1)(A) of the HPSAs with the greatest shortages. This notice sets forth revised criteria for determining mental health HPSAs with the greatest shortage. This updates the previous criteria published on May 30, 2003.

DATES: Effective January 14, 2015.

FOR FURTHER INFORMATION CONTACT: Kae Brickerd, Ph.D., Chief, Shortage Designation Branch, Bureau of Health Workforce, Division of Policy and Shortage Designation, Health Resources and Services Administration, 11W14 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, 301 945–0828, *kbrickerd@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Section 332 of the PHS Act, 42 U.S.C. 254e, provides that the Secretary shall designate HPSAs based on criteria established by regulation. HPSAs are defined in Section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. The required regulations setting forth the criteria for designating HPSAs are codified at 42 CFR part 5. Section 333A(a)(1)(A) of the PHS Act and requires that the Secretary give priority in the assignment of National Health Service Corps personnel to entities serving HPSAs with the greatest health professional shortage. Section 333A(b) of the PHS Act requires that the Secretary establish criteria specifying the manner in which she determines HPSAs of greatest shortage and publish the criteria, and any revisions to the criteria, in the **Federal Register**. The criteria established by the Secretary create a method for scoring HPSAs based on relative shortage.

In the **Federal Register** notice on May 30, 2003, 68 FR 32531, the following criteria were identified for determining scores for mental health HPSAs: population to provider ratio, percentage of the population below 100 percent of poverty, travel time to the nearest alternative source of care, the ratio of children under age 18 to adults age 18–64, the ratio of adults over age 65 to adults age 18–64, and alcohol and substance abuse prevalence rates. Each factor is given points and the score is the sum of the points, up to 25. This notice modifies and provides clarification to the point scale for the population to provider ratio component of the formula, based on an assessment that the current point scale for the population to provider ratio does not adequately reflect the level of shortage. As a result of the modifications, the point values assigned for some population to provider ratios will see either a small increase or decrease, while others may remain unchanged. All other scoring criteria and point scales remain the same as published in the previous notice.

The point scale published in 2003 for the population to provider ratio is presented in the following table:

Psychiatrist ratio	Core mental health ratio	Score
>45,000:0 AND	>4,500:0	8
	>4500:1 and <6000:1[1]	7
<20,000:1 and >15,000:1 AND	>6000:1 and <9,000:1	6
<30,000:1 and >15,000:1 OR	>4,500:1 and <6,000:1	5
<45,000:1 and > 20,000:1 AND	>4,500:0 and <6,000:0	4
>20,000:1 AND	>6,000:1	3
>30,000:1		2
	>9,000:1	1

[1] > = Greater Than; < = Less Than

To reflect the mental health services available in a community, entities applying for Mental Health HPSAs are encouraged to report on the number of both psychiatrists and core mental health providers rendering services. The revised point scale is as follows:

For Geographic High Need and Population HPSAs, as defined in the designation criteria set forth in 42 CFR part 5, Appendix C, Part 1, and A.4.

BILLING CODE 4165–15–P