III. Hearing Procedures

In accordance with section 505(e) of the FD&C Act, Watson Laboratories, Inc. is hereby provided an opportunity to request a hearing to show why approval of ANDA 078394 should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug product covered by this application.

An applicant who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the application and constitutes a waiver of any contentions concerning the legal status of the drug product. FDA will then withdraw approval of the application, and the drug product may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

Paper submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Letter from Leslie Ball, FDA, to Roger Hayes, Cetero Research, July 26, 2011.
2. FDA, ''Notification to Pharmaceutical Companies: Acceptance of third-party data integrity audit for Cetero studies conducted from March 1, 2008, to August 31, 2009'' (*https://wayback.archive-it.org/7993/20170113203457/http:/www.fda.gov/Drugs/DrugSafety/ucm265559.htm*), accessed September 10, 2019.
3. Letter from Keith Webber, FDA, to Watson Laboratories, Inc., August 9, 2011.
4. Letter from Carol A. Holquist, FDA, to Watson Laboratories, Inc., August 19, 2016.
5. Letter from Carol A. Holquist, FDA, to Watson Laboratories, Inc., April 24, 2017.

Dated: October 21, 2019.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2019–23490 Filed 10–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4657]

Science Advisory Board to the National Center for Toxicological Research Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Science Advisory Board to the National Center for Toxicological Research. The general function of the committee is to provide advice and recommendations to the Agency on research being conducted at the National Center for Toxicological Research. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on December 3, 2019 from 8 a.m. to 5:55 p.m., and on December 4, 2018 from 8 a.m. to 11:30 a.m.

ADDRESSES: Heifer Village, 1 World Ave., Little Rock, AR 72202. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* and *https://www.heifer.org/what-you-can-do/experience-heifer/heifer-village/index.html.*

FOR FURTHER INFORMATION CONTACT: Donna Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993–0002, 301–796–8892, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATON: *Agenda:* On December 3, 2019, the Science Advisory Board Chair will welcome the participants, and the NCTR Director will provide a Center-wide update on scientific initiatives and accomplishments during the past year. The Science Advisory Board will be presented with an overview of the Science Advisory Board Subcommittee Site Visit Report and a response to this review. The Center for Biologics and Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, the Center for Tobacco Products and the Office of Regulatory Affairs will each briefly discuss their specific research strategic needs and potential areas of collaboration.

On December 4, 2019, there will be updates from the NCTR Research Divisions and a public comment session. Following an open discussion

of all the information presented, the open session of the meeting will close so the SAB members can discuss personnel issues at NCTR at the end of the day.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On December 3, 2019, from 8 a.m. to 5:55 p.m., and December 4, 2019, from 8 a.m. to 11:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 26, 2019. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 3, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 18, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 19, 2019.

Closed Committee Deliberations: On December 4, 2019, from 11:30 a.m. to 12:00 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Donna Mendrick at least 14 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23413 Filed 10–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an Anti-GPC3 Radionuclide Immunoconjugate for the Treatment of GPC3-Expressing Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Xsto BioSciences, Inc. (Xsto), located in San Carlos, California.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before November 12, 2019 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702 Telephone: (240)–276–5530; Facsimile: (240)–276–5504 Email: *david.lambertson@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 61/477,020 entitled ''Human Monoclonal Antibody Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–US–01], PCT Patent Application PCT/US2012/034186 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–PCT–02], Chinese Patent 201280029201.3 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–CN–03], European Patent 2699603 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–EP–04], and validated in France [HHS Ref. E–130–2011–0–FR–09], Germany [HHS Ref. E–130–2011–0–DE–08] and the United Kingdom [HHS Ref. E–130–2011–0–GB–10] and lodged in Hong Kong [HHS Ref. E–130–2011–0–HK–11], United States Patent 9,206,257 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–US–05], United States Patent 9,394,364, entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–US–06], European Patent 2998320 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–EP–07], and validated in France [HHS Ref. E–130–2011–0–FR–23], Germany [HHS Ref. E–130–2011–0–DE–22] and the United Kingdom [HHS Ref. E–130–2011–0–GB–24], United States Patent 9,932,406 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–US–12], Chinese Patent Application 201610290837.3 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–CN–13], European Patent 3070104 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–EP–14], and validated in France [HHS Ref. E–130–2011–0–FR–18], Germany [HHS Ref. E–130–2011–0–DE–16], the United Kingdom [HHS Ref. E–130–2011–0–GB–19], Italy [HHS Ref. E–130–2011–0–IT–20] and Spain [HHS Ref. E–130–2011–0–ES–17] and lodged in Hong Kong [HHS Ref. E–130–2011–0–HK–15], United States Patent Application 15/843,256 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use