initially sterile topical solutions become contaminated with bacteria during the course of treatment.[3] If the product were to become contaminated with bacteria present on or around the surface of one eye, and the same bottle of product is used in both eyes, the patient could transmit the bacteria from one eye to the other.

The clinical studies conducted by ISTA supporting approval of Bromday and Xibrom specifically excluded treatment of both eyes and excluded the concomitant use of other nonsteroidal anti-inflammatory drugs. There are no data in the application supporting the safe use of a single bottle in more than one eye. ISTA's supplement 15 contained no information, data, or analysis relevant to these risks. As with any NDA, the sponsor bears the burden of supplying necessary data and information to demonstrate safety, and this includes satisfying CDER that a specific safety concern has been adequately addressed. Accordingly, the supplement lacks data, information, or analysis that would allay CDER's concerns about the potential risks associated with the larger fill size. We note that although we did not consider this safety issue at the time of initial approval of Xibrom and certain other products for which this issue may be relevant, as this issue develops, we also intend to take appropriate steps with respect to other products that raise the issue.

III. Notice of Opportunity for a Hearing

For the reasons summarized previously, notice is given to ISTA Pharmaceuticals, Inc., and to all other interested persons, that the Center Director proposes to issue an order under section 505(d) of the FD&C Act refusing to approve supplement 15 to NDA 21–664 on the grounds that ISTA did not include data, information, or analysis sufficient to show that Bromday would be safe for use as labeled if supplied in the proposed 2.4 mL fill size. Specifically, the investigations conducted by ISTA in support of supplement 15 do not include adequate tests by all methods reasonably applicable to show whether or not Bromday would be safe for use as labeled if supplied in the proposed 2.4 mL fill size (section 505(d)(1) of the FD&C Act; § 314.125(b)(2) (21 CFR 314.125(b)(2)), and ISTA did not provide sufficient information about the proposed 2.4 mL fill size to permit CDER to determine whether Bromday is safe for use under the conditions prescribed, recommended, or suggested by its labeling if supplied in a 2.4 mL fill size (section 505(d)(4) of the FD&C Act; § 314.125(b)(4)).

ISTA may request a hearing before the Commissioner of Food and Drugs (the Commissioner) on the Center Director's proposal to refuse to approve supplement 15 to NDA 21–664. If ISTA decides to seek a hearing, it must file: (1) A written notice of participation and request for a hearing (see the **DATES** section of this document); and (2) the studies, data, information, and analyses relied upon to justify a hearing (see the **DATES** section of this document), as specified in § 314.200. As stated in § 314.200(g), 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 to resolve. The failure to request a hearing within the time provided and in the manner required by § 314.200 constitutes a waiver of the opportunity to request a hearing. If a hearing request is not properly submitted, FDA will issue a notice refusing to approve supplement 15 to NDA 21–664.

The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest (§ 314.200(g)(6)). If a hearing is granted, it will be conducted according to the procedures provided in 21 CFR parts 10 through 16 and 21 CFR 314.201.

Paper submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and on the Internet at *http://www.regulations.gov*. This notice is issued under section 505(c)(1)(B) of the FD&C Act, §§ 314.110(b)(3) and 314.200, and under authority delegated to the Director of CDER.

Dated: July 28, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19566 Filed 8–2–11; 8:45 am]

BILLING CODE 4160–01–P

[3] Jokl D.H. *et al.,* ''Bacterial Contamination of Ophthalmic Solutions Used in an Extended Care Facility,'' *British Journal of Ophthalmology,* 91:1308–1310, 2007.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Physiological Chemistry and Genomics.

Date: August 15, 2011.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ronald Adkins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301–495–4511, *ronald.adkins@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 28, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–19695 Filed 8–2–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.