the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body—(OMB Control Number 0910–0374)—Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997, provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences (NAS). Under this section of the FD&C Act, a person that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the **Federal Register** of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body.'' The guidance provides the Agency's interpretation of terms central to the submission of a notification and the Agency's views on the information that should be included in the notification. The Agency believes that the guidance will enable persons to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act. In addition to the information specifically required by the FD&C Act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. FDA intends to review the notifications the Agency receives to ensure that they comply with the criteria established by the FD&C Act.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	1	1	1	450	450
Guidance for Notifications	2	1	2	1	2
Total					702

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with health claims, nutrient content claims, and other similar notification procedures that fall under our jurisdiction. To avoid estimating the number of respondents as zero, the Agency estimates that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. FDA estimates that it will receive one nutrient content claim notification and one health claim notification per year over the next 3 years.

Section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act requires that the notification include the exact words of the claim, a copy of the authoritative statement, a concise description of the basis upon which such person relied for determining that this is an authoritative statement as outlined in the FD&C Act, and a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which a health claim refers or to the nutrient level to which the nutrient content claim refers. This balanced representation of the scientific literature is expected to include a bibliography of the scientific literature on the topic of the claim and a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement.

Since the claims are based on authoritative statements of a scientific body of the U.S. Government or NAS, FDA believes that the information that is required by the FD&C Act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, FDA estimates that 1 respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, FDA estimates that 1 respondent will take 450 hours to collect and assemble the information required by the statute for a health claim notification.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. FDA has determined that this information should be readily available to a respondent and, thus, the Agency estimates that it will take a respondent 1 hour to incorporate the information into each notification. The Agency expects there will be 2 respondents for a total of 2 hours.

Dated: July 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–19601 Filed 8–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0513]

Proposal To Refuse To Approve a Supplemental New Drug Application for Bromday (Bromfenac Ophthalmic Solution), 0.09%; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), the Director of

the Center for Drug Evaluation and Research (the Center Director), is proposing to refuse to approve a supplemental new drug application submitted by ISTA Pharmaceuticals, Inc. (ISTA), for a new 2.4 milliliter (mL) fill size for Bromday (bromfenac ophthalmic solution), 0.09%. This notice summarizes the grounds for the proposal of the Center for Drug Evaluation and Research (CDER) and offers ISTA an opportunity to request a hearing on the matter.

DATES: Submit written requests for a hearing by September 2, 2011; submit data in support of the hearing request by October 3, 2011.

ADDRESSES: Submit electronic or written requests for a hearing; any data, information, and analyses justifying the hearing; and any other comments. Submit electronic requests and supporting documents to *http://www.regulations.gov,* or submit written requests and supporting documents to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify both electronic and written requests and the supporting documents with the docket number in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6368, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

On March 24, 2005, FDA approved ISTA's new drug application (NDA) 21–664 to market Xibrom (bromfenac sodium ophthalmic solution), 0.09%. On October 16, 2010, FDA approved Bromday (bromfenac ophthalmic solution), 0.09%, through a supplement to NDA 21–664. Xibrom and Bromday are topical ophthalmic solutions supplied as sterile, aqueous eye drops and approved for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction. Xibrom is applied to the affected eye twice daily for 2 weeks beginning 24 hours after surgery, whereas Bromday is applied to the affected eye once daily beginning 1 day before surgery and continuing on the day of surgery and for 14 days thereafter. Xibrom currently is approved in 2.5 mL and 5 mL fill sizes, but, as discussed below, the Center is considering steps to address the safety concerns relating to the larger fill size. Bromday is approved in a 1.7 mL fill size.

ISTA submitted supplement 15 to the Xibrom/Bromday NDA on October 18, 2010, seeking approval to market Bromday in a 2.4 mL fill size. ISTA has stated—in its cover letter accompanying supplement 15 and in its request for an opportunity for a hearing—that patients often have cataract removal surgeries in both eyes, and that the 1.7 mL fill size does not contain a sufficient volume of product to treat two eyes for a full course of treatment. The Division of Anti-Infective and Ophthalmology Products (DAIOP) [1] within CDER issued a complete response letter on February 18, 2011, determining that it could not approve supplement 15 in its present form, stating: (1) That the data submitted do not justify the need for increasing the fill volume and creating a new trade size; (2) that current fill volume appears to contain sufficient drug product for a full course of treatment; and (3) that a single bottle of Bromday should not be used to treat more than one eye in a postoperative setting. Furthermore, the February 18, 2011, complete response letter states that ISTA is required to resubmit the application or take other actions available under § 314.110 (21 CFR 314.110) (*i.e.,* withdraw the application or request an opportunity for a hearing).

On May 12, 2011, ISTA submitted a request for an opportunity for a hearing under § 314.110(b)(3) on whether there are grounds under section 505(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(d)) for denying approval of supplement 15. Officials from CDER, including the Director of the Office of Antimicrobial Products (OAP), Dr. Edward Cox, held a telephone conference with ISTA on June 22, 2011, and explained that ISTA has not adequately justified the need for a larger fill volume, and that CDER believes that use of a single bottle of Bromday to treat two eyes unacceptably and unnecessarily increases the risk of microbial infection. Accordingly, CDER officials explained that, based on the information before them, they intended to deny approval of supplement 15, but that they are considering whether to present the issue of fill sizes for postoperative topical ophthalmic products to an advisory committee. ISTA was asked whether it would agree to extend the 60-day timeframe for FDA to respond to its request for notice of an opportunity for a hearing (§ 314.110(b)(3)) until after an advisory committee has met, but ISTA has not agreed to such an extension. CDER continues to consider the issue as it relates to other postoperative topical ophthalmic products.

[1] Because of a recent reorganization in the Office of Antimicrobial Products, the Division of Transplant and Ophthalmology Products is now responsible for reviewing the supplement.

II. Proposal To Refuse To Approve Supplement 15 to NDA 21–664

Under § 314.200(a) (21 CFR 314.200(a)), this notice describes the reasons for the Center's proposal to refuse to approve supplement 15 to NDA 21–664 and the proposed grounds for the order.

ISTA submitted supplement 15 to NDA 21–664, under section 505(b)(1) of the FD&C Act, proposing to market Bromday in a 2.4 mL fill size. ISTA was required to submit, among other things, ''full reports of investigations which have been made to show whether or not such drug is safe for use'' if supplied in the proposed larger fill size (section 505(b)(1)(A) of the FD&C Act). CDER has concluded, however, that ISTA did not provide sufficient data, analysis, and information to determine that Bromday would be safe for use if supplied in the proposed larger fill size.

Specifically, CDER believes that the existing fill size is adequate to treat a single eye. CDER further believes that the proposed larger fill size, for the purpose of treating two eyes with a single bottle, may pose a potential risk of microbial infection associated with use of the product, and that ISTA has not adequately justified the need for that larger fill size. Microbial infection is a significant concern for ophthalmic products with postoperative indications, because an eye whose surface is compromised by a surgical procedure is more prone to infection than an eye with an intact cornea.[2]

The contents of the Bromday bottle could become contaminated with harmful bacteria if the patient accidentally causes the dropper tip to come into contact with any nonsterile surface. Bromday contains benzalkonium chloride as a preservative, but this ingredient only reduces, and does not eliminate, the risk of microbial contamination. Further, although the Bromday labeling advises that patients should ''not touch [the] dropper tip to any surface, as this may contaminate the contents,'' patients may accidentally touch the dropper tip to the surface of the eye or the skin around the eye, which may lead to microbial contamination of the bottle contents. Accordingly, it is not uncommon that

[2] See, for example, Yanoff, M. and Duker, *Ophthalmology,* Mosby, 2009 and Arffa, R., *Grayson's Diseases of the Cornea,* Mosby, 1991.

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.