

- Ph+ CML in CP with the T315I mutation.

Subsequent to this approval, the USPTO received a patent term restoration application for SCEMBLIX (U.S. Patent No. 8,829,195) from Novartis AG, and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated January 10, 2023, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SCEMBLIX represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SCEMBLIX is 2,845 days. Of this time, 2,717 days occurred during the testing phase of the regulatory review period, while 128 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* January 16, 2014. The applicant claims December 17, 2013, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 16, 2014, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 24, 2021. FDA has verified the applicant's claim that the new drug application (NDA) for SCEMBLIX (NDA 215358) was initially submitted on June 24, 2021.

3. *The date the application was approved:* October 29, 2021. FDA has verified the applicant's claim that NDA 215358 was approved on October 29, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 899 days of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**).

Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 21, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–28519 Filed 12–26–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2022–E–0926]

### Determination of Regulatory Review Period for Purposes of Patent Extension; CYTALUX

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for CYTALUX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by February 26, 2024. Furthermore, any interested person may

petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 24, 2024. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 26, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–

2022-E-0926 for “Determination of Regulatory Review Period for Purposes of Patent Extension; CYTALUX.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, CYTALUX (pafolacianine), which is indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions. Subsequent to this approval, the USPTO received a patent term restoration application for CYTALUX (U.S. Patent No. 9,061,057) from Purdue Research Foundation, and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated September 21, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of CYTALUX represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for CYTALUX is 2,610 days. Of this time, 2,274 days occurred during the testing phase of the regulatory review period, while 336 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 9, 2014. The applicant claims September 5, 2014, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 9, 2014, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 29, 2020. FDA has verified the applicant’s claim that the new drug application (NDA) for CYTALUX (NDA 214907) was initially submitted on December 29, 2020.

3. *The date the application was approved:* November 29, 2021. FDA has verified the applicant’s claim that NDA 214907 was approved on November 29, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 825 days of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th

Cong., 2d sess., pp. 41–42, 1984.)  
Petitions should be in the format  
specified in 21 CFR 10.30.

Submit petitions electronically to  
<https://www.regulations.gov> at Docket  
No. FDA–2013–S–0610. Submit written  
petitions (two copies are required) to the  
Dockets Management Staff (HFA–305),  
Food and Drug Administration, 5630  
Fishers Lane, Rm. 1061, Rockville, MD  
20852.

Dated: December 21, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–28507 Filed 12–26–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–F–5500]

#### **Kemin Industries, Inc.; Filing of Food Additive Petition (Animal Use); Chromium Propionate; Correction**

**AGENCY:** Food and Drug Administration,  
HHS

**ACTION:** Notification of petition;  
correction.

**SUMMARY:** The Food and Drug  
Administration is correcting a notice  
entitled “Kemin Industries, Inc.; Filing  
of Food Additive Petition (Animal Use)”  
that appeared in the **Federal Register**  
of July 27, 2023. The document announced  
that we filed a petition, submitted by  
Kemin Industries, Inc., proposing that  
the food additive regulations be  
amended to provide for the safe use of  
chromium propionate to be used as a  
source of chromium in turkey feed. The  
document was published with an  
incorrect docket number. This  
document corrects that error.

#### **FOR FURTHER INFORMATION CONTACT:**

Wasima Wahid, Center for Veterinary  
Medicine (HFV–221), Food and Drug  
Administration, 12225 Wilkins Ave.,  
Rockville, MD 20852, 240–402–5857,  
[wahima.wahid@fda.hhs.gov](mailto:wahima.wahid@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the  
**Federal Register** of Thursday, July 27,  
2023 (88 FR 48406) in FR Doc. 2023–  
15913, the following correction is made:

On page 48406, in the first column, in  
the header of the document, “Docket  
No. FDA–2023–F–2415” is corrected to  
read “Docket No. FDA–2023–F–5500”.

Dated: December 21, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–28512 Filed 12–26–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Institute of Nursing Research; Notice of Closed Meeting**

Pursuant to section 1009 of the  
Federal Advisory Committee Act, as  
amended, 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:* National Institute of  
Nursing Research Special Emphasis Panel;  
NRRC Member Conflict Meeting.

*Date:* February 2, 2024.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant  
applications.

*Place:* National Institute of Nursing  
Research, 6701 Democracy Boulevard,  
Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Nisan Bhattacharyya,  
Ph.D., Scientific Review Officer, Scientific  
Review Branch, National Institute of Nursing  
Research, NIH, 6701 Democracy Boulevard,  
Suite 668, Bethesda, MD 20892, 301–451–  
2405, [nisan.bhattacharyya@nih.gov](mailto:nisan.bhattacharyya@nih.gov).

(Catalogue of Federal Domestic Assistance  
Program Nos. 93.361, Nursing Research,  
National Institutes of Health, HHS)

Dated: December 21, 2023.

**Victoria E. Townsend,**

*Program Analyst, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 2023–28566 Filed 12–26–23; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings**

Pursuant to section 1009 of the  
Federal Advisory Committee Act, as  
amended, notice is hereby given of the  
following meetings.

The meetings 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:* National Institute on  
Deafness and Other Communication  
Disorders Special Emphasis Panel; Initiation  
of NIDCD Hearing and Balance Translational  
Application.

*Date:* January 22, 2024.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant  
applications.

*Place:* National Institutes of Health,  
Neuroscience Center, 6001 Executive  
Boulevard, Rockville, MD 20852 (Virtual  
Meeting).

*Contact Person:* Shiguang Yang, DVM,  
Ph.D., Scientific Review Officer, Division of  
Extramural Activities, NIDCD, NIH, 6001  
Executive Blvd., Room 8349 Bethesda, MD  
20892, 301–496–8683, [yangshi@nidcd.nih.gov](mailto:yangshi@nidcd.nih.gov).

*Name of Committee:* National Institute on  
Deafness and Other Communication  
Disorders Special Emphasis Panel; Review of  
NIDCD Research Grant Applications for  
Translating Basic Research in Voice, Speech,  
and Language into Clinical Tools.

*Date:* January 29, 2024.

*Time:* 2:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant  
applications.

*Place:* National Institutes of Health,  
Neuroscience Center, 6001 Executive  
Boulevard, Rockville, MD 20852 (Virtual  
Meeting).

*Contact Person:* Sonia Elena Nanesco,  
Ph.D., Scientific Review Officer, Division of  
Extramural Activities, NIDCD, NIH, 6001  
Executive Blvd., Suite 8300, Bethesda, MD  
20892, (301) 496–8683, [sonia.nanesco@nih.gov](mailto:sonia.nanesco@nih.gov).

*Name of Committee:* National Institute on  
Deafness and Other Communication  
Disorders Special Emphasis Panel; NIDCD  
Clinical Research Center Grant (P50) Review.

*Date:* January 31, 2024.

*Time:* 1:30 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant  
applications.

*Place:* National Institutes of Health,  
Neuroscience Center, 6001 Executive  
Boulevard, Rockville, MD 20852 (Virtual  
Meeting).

*Contact Person:* Kausik Ray, Ph.D.,  
Scientific Review Officer, National Institute  
on Deafness and Other Communication  
Disorders, National Institutes of Health, 6001  
Executive Blvd., Rockville, MD 20852, 301–  
402–3587, [rayk@nidcd.nih.gov](mailto:rayk@nidcd.nih.gov).

*Name of Committee:* Communication  
Disorders Review Committee

*Date:* February 1–2, 2024.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant  
applications.

*Place:* Delta Hotels by Marriott at  
Anaheim-Garden Grove, Anaheim, CA 92840.

*Contact Person:* Katherine Shim, Ph.D.,  
Scientific Review Officer, Division of