

information sharing. AHRQ personnel are able to systematically search the information collected and stored in the ARRS database. Personnel will also use the information to address internal and/or external requests for information regarding grant progress, preliminary findings, and other requests, such as Freedom of Information Act requests, and producing responses related to

federally mandated programs and regulations.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the respondents. It will take grantees and vendors an estimated 15 minutes to enter the necessary data into the ARRS System and reporting will occur four

times annually. The total annualized burden hours are estimated to be 500 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents. The total estimated cost burden for respondents is \$19,710.

**Exhibit 1 Estimated Annualized Burden Hours**

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Data entry into ARRS .....	500	4	15/60	500
Total .....	500	N/A	N/A	500

**Exhibit 2 Estimated Annualized Cost Burden**

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Data entry into ARRS .....	500	500	\$39.42	\$19,710
Total .....	500	500	N/A	19,710

\* Based upon the average wages for Healthcare Practitioner and Technical Occupations (29-0000), "National Compensation Survey: Occupational Wages in the United States, May 2015," U.S. Department of Labor, Bureau of Labor Statistics, [http://www.bls.gov/oes/current/oes\\_nat.htm#29-0000](http://www.bls.gov/oes/current/oes_nat.htm#29-0000).

**Request for Comments**

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 26, 2020.  
**Virginia L. Mackay-Smith**,  
*Associate Director.*  
 [FR Doc. 2020-04277 Filed 3-2-20; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-D-4436]

**Bone Anchors—Premarket Notification (510(k)) Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Bone Anchors—Premarket Notification (510(k)) Submissions." This guidance document provides recommendations for 510(k) submissions for bone anchor (suture anchor) devices. FDA is clarifying and providing current thinking on the recommended content for a bone anchor 510(k) submission, including performance testing recommendations and device description.

**DATES:** The announcement of the guidance is published in the **Federal Register** on March 3, 2020.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

*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-2016-D-4436 for “Bone Anchors—Premarket Notification (510(k)) Submissions.” Received comments 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.

- **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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Bone Anchors—Premarket Notification (510(k)) Submissions” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Laurence Coyne, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4512, Silver Spring, MD 20993-0002, 301-796-6450.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This guidance document provides recommendations for 510(k) submissions for bone anchor (suture anchor) devices, which are indicated for attachment of soft tissue to bone. FDA is clarifying and providing current thinking on the recommended content

for a bone anchor 510(k) submission, including performance testing recommendations and device description. FDA considered comments received on the draft guidance that appeared in the **Federal Register** of January 3, 2017 (82 FR 128). FDA revised the guidance as appropriate in response to the comments.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Bone Anchors—Premarket Notification (510(k)) Submissions.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “Bone Anchors—Premarket Notification (510(k)) Submissions” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1400005 and the complete guidance title to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the following regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910-0120
812 .....	Investigational Device Exemption .....	0910-0078
801 .....	Medical Device Labeling Regulations .....	0910-0485
820 .....	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation .....	0910-0073

Dated: February 27, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-04361 Filed 3-2-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-P-3082]

#### Determination That NEO TECT KIT (Kit for the Preparation of Technetium Tc-99m Depreotide Injection) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to the product, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Michelle T. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993-0002, 240-402-0374, *Michelle.Weiner@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was approved previously. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the

“Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but it must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) is the subject of NDA 021012, currently held by CIS Bio International SA, approved on August 3, 1999. NEO TECT KIT is a scintigraphic imaging agent that identifies somatostatin receptor-bearing pulmonary masses in patients presenting with pulmonary lesions on computed tomography and/or chest x ray who have known malignancy or who are highly suspect for malignancy.

NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) is listed as Discontinued in the Orange Book. Andarix Pharmaceuticals, Inc. submitted a citizen petition dated June 25, 2019 (Docket No. FDA-2019-P-3082), under 21 CFR 10.30, requesting that the Agency determine whether NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) was withdrawn from sale voluntarily for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records with respect to NEO TECT KIT and based on the information we have at this time, FDA has determined under § 314.161 that NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) was not withdrawn from sale for reasons of safety or effectiveness. FDA carefully reviewed its files for records concerning the withdrawal of NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) from sale. In addition, the Agency independently evaluated relevant literature and data for possible post-marketing adverse events. We have found no information that would indicate that this drug

product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 24, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-04319 Filed 3-2-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2018-E-2615 and FDA-2018-E-2616]

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

**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 ILUMYA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 biological product.

**DATES:** Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by May 4, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for