NUBEQA is 2,576 days. Of this time, 2,420 days occurred during the testing phase of the regulatory review period, while 156 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:* July 13, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 13, 2012.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* February 26, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for NUBEQA (NDA 212099) was initially submitted on February 26, 2019.

3. *The date the application was approved:* July 30, 2019. FDA has verified the applicant's claim that NDA 212099 was approved on July 30, 2019.

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 879 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: October 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23074 Filed 10–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0548]

Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Draft Guidance for Industry; 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 draft guidance for industry entitled ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data.'' This guidance provides recommendations to sponsors to help support compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) when submitting study data derived from real-world data (RWD) sources in applicable regulatory submissions using standards specified in the Data Standards Catalog (Catalog). FDA is publishing this draft guidance as part of a series of guidance documents under its program to evaluate the use of real-world evidence (RWE) in regulatory decision making.

DATES: Submit either electronic or written comments on the draft guidance by December 21, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2021–D–0548 for ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data.'' 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, 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 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.

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–3161, *Dianne.Paraoan@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data.'' Under section 745A(a) of the FD&C Act (21 U.S.C. 379k–1(a)) and the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (Study Data Guidance), clinical or nonclinical study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs) must be in an electronic format that the Agency can process, review, and archive, unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver. This guidance clarifies that RWD submitted as study data in NDAs, ANDAs, certain BLAs, and certain INDs are subject to the requirements in section 745A(a) of the FD&C Act (21 U.S.C. 379k–1(a)) and the Study Data Guidance. Currently, as stated in the Study Data Guidance, the Agency can process, review, and archive electronic submissions of clinical and nonclinical study data (including data derived from RWD sources) that use the standards specified in the Catalog posted to FDA's Study Data Standards Resources web page (*https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources*). Therefore, submissions subject to section 745A(a) of the FD&C Act that contain study data derived from RWD sources must be in electronic format using the study data standards currently supported by FDA as specified in the Catalog. This guidance provides recommendations to sponsors for complying with section 745A(a) of the FD&C Act when submitting study data derived from RWD sources in an applicable regulatory submission using standards specified in the Catalog.

Section 3022 of the 21st Century Cures Act (Cures Act) amended the FD&C Act to add section 505F, Utilizing Real World Evidence (21 U.S.C. 355g). This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help support or satisfy postapproval study requirements. This section also requires that FDA use the program to inform guidance for industry on the circumstances under which sponsors of drugs may rely on RWE and the appropriate standards and methodologies for collection and analysis of RWE submitted to evaluate the potential use of RWE for those purposes. Further, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA committed to publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions. FDA is issuing the draft guidance entitled ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data'' as part of a series of guidance documents to satisfy the Cures Act mandate and the PDUFA VI commitment.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 (Applications for FDA Approval to Market a New Drug) have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 (Investigational New Drug Regulations) have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 58 (Good Laboratory Practice Regulations for Nonclinical Laboratory Studies) have been approved under OMB control number 0910–0119; and the collections of information in 21 CFR part 601 (General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension) have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: October 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23081 Filed 10–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1038]

Determination That ROBAXIN and ROBAXIN–750 (Methocarbamol), Oral Tablets, 500 Milligrams and 750 Milligrams, and Other Drug Products, Were 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 the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 011011	ROBAXIN; ROBAXIN–750.	Methocarbamol	500 milligrams (mg); 750 mg.	Tablet; Oral	Auxilium Pharmaceuticals LLC.
NDA 018704	LOPRESSOR	Metoprolol Tartrate	1 mg/milliliter (mL)	Injectable; Injection	Novartis.
NDA 018917	SECTRAL	Acebutolol Hydrochloride.	Equivalent to (EQ) 200 mg base; EQ 400 mg base.	Capsule; Oral	Promius Pharma, LLC.
NDA 019546	DYNACIRC	Isradipine	2.5 mg; 5 mg	Capsule; Oral	SmithKline Beecham.
NDA 019555	DIPROLENE AF	Betamethasone Dipropionate.	EQ 0.05% base	Cream, Augmented; Topical.	Merck Sharp Dohme.
NDA 019625	ELOCON	Mometasone Furoate	0.10%	Cream; Topical	Merck Sharp Dohme.
NDA 020089	ZOVIRAX	Acyclovir	400 mg; 800 mg	Tablet; Oral	Mylan.
NDA 020136	DEMADEX	Torsemide	5 mg; 10 mg; 20 mg; 100 mg.	Tablet; Oral	Mylan Specialty, L.P.
NDA 020198	ADALAT CC	Nifedipine	30 mg; 60 mg; 90 mg	Tablet, Extended Release; Oral.	Alvogen.
NDA 020539	LAMISIL	Terbinafine Hydrochloride.	EQ 250 mg base	Tablet; Oral	Novartis.
NDA 020634	LEVAQUIN	Levofloxacin	250 mg; 500 mg; 750 mg.	Tablet; Oral	Janssen Research & Development, LLC.
NDA 020716	VICOPROFEN	Hydrocodone Bitartrate; Ibuprofen.	7.5 mg; 200 mg	Tablet; Oral	Abbvie, Inc.
NDA 020738	TEVETEN	Eprosartan Mesylate	EQ 300 mg base; EQ 400 mg base; EQ 600 mg base.	Tablet; Oral	Abbvie, Inc.
NDA 021001	AXERT	Almotriptan Malate	EQ 6.25 mg base; EQ 12.5 mg base.	Tablet; Oral	Janssen Pharms.
NDA 022205	GIAZO	Balsalazide Disodium	1.1 gram	Tablets; Oral	Valeant Pharms. International.
NDA 022439	ZUTRIPRO	Chlorpheniramine Maleate, Hydrocodone Bitartrate, and Pseudoephedrine Hydrochloride.	4 mg/5 mL; 5 mg/5 mL; 60 mg/5 mL.	Solution; Oral	Persion Pharms, LLC.