

Application No.	Drug	Applicant
NDA 019916	Morphine Sulfate Injection, 1 mg/mL and 5 mg/mL	Do.
NDA 020593	Depacon (valproate sodium) Injection, Equivalent to (EQ) 100 mg base/mL	AbbVie, Inc.
NDA 020634	Levaquin (levofloxacin) Tablets, 250 mg, 500 mg, and 750 mg	Janssen Pharmaceuticals, Inc.
NDA 021241	Ortho Tri-Cyclen Lo (ethinyl estradiol and norgestimate) Oral-28 (White) Tablets, 0.025 mg ethinyl estradiol and 0.18 mg norgestimate; (Light Blue) Tablets, 0.025 mg ethinyl estradiol and 0.215 mg norgestimate; (Dark Blue) Tablets, 0.025 mg ethinyl estradiol and 0.250 mg norgestimate.	Do.
NDA 206544	MorphaBond ER (morphine sulfate) Extended-Release Tablets, 15 mg, 30 mg, 60 mg, and 100 mg.	Daiichi Sankyo, Inc., 211 Mount Airy Rd., Basking Ridge, NJ 07920.
NDA 208399	Varubi (rolapitant HCl) Injectable Emulsion, EQ 166.5 mg base/92.5 mL (EQ 1.8 mg base/mL).	TerSera Therapeutics LLC, 520 Lake Cook Rd., suite 500, Deerfield, IL 60015.
NDA 209203	Duzallo (allopurinol and lesinurad) Tablets, 200 mg/200 mg and 300 mg/200 mg.	Ironwood Pharmaceuticals, Inc., 100 Summer St., suite 2300, Boston, MA 02110.
NDA 210895	Welchol (colesevelam HCl) Chewable Bars, 3.75 g	Daiichi Sankyo, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 22, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on January 22, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-28346 Filed 12-22-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures; Correction of Extension Date

AGENCY: Office of the Secretary (OS), DHHS.

ACTION: Correction.

SUMMARY: This document updates the July 30, 2020, **Federal Register** Notice entitled “Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures,” by

revising the last sentence in the “Summary” section.

FOR FURTHER INFORMATION CONTACT: Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of Strategy, Policy, Planning, and Requirements, Suite 5440—O’Neill House Office Building, 200 C Street SW, Washington, DC 20201, (202) 260-0365.

SUPPLEMENTARY INFORMATION:

I. Correction of Errors

In FR Doc. 2020-16458 of July 30, 2020 (85 FR 45895-45897), make the following corrections:

On page 48596, first full column, **SUMMARY** section, change second to last sentence to “This notice, issued on July 23, 2020, extends the March 25 Designation Notice to January 19, 2021.” The expiration date, January 19, 2021 is not 120 days from the date of issuance so remove that reference.

Wilma Robinson,

Deputy Executive Secretary, Department of Health and Human Services.

[FR Doc. 2020-28374 Filed 12-22-20; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be open to the public via NIH videocast. The URL link to this meeting is <https://videocast.nih.gov/watch=38984>.

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 Advisory Dental and Craniofacial Research Council.

Date: January 27, 2021.

Open: 10:00 a.m. to 1:05 p.m.

Agenda: Report of the Director, NIDCR
Place: National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Room 662 Bethesda, MD 20892, (Virtual Meeting).

Closed: 1:20 p.m. to 2:00 p.m.

Agenda: Grant applications.

Place: National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Room 662 Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Room 662, Bethesda, MD 20892, 301-594-4805, adombroski@nidcr.nih.gov.

Any interested person may file written comments with the committee no later than 15 days after the meeting by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute’s/Center’s home page: <http://www.nidcr.nih.gov/about>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)