Application No.	Drug	Applicant
NDA 016418	INDERAL (propranolol HCl) Tablet; Oral, 80 mg	Wyeth Pharmaceuticals Inc., C/O Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 016909	LIDEX (fluocinonide) Ointment; Topical 0.05%	County Line Pharmaceuticals, LLC, 13890 Bishop's Dr., Suite 410, Brookfield, WI 53005.
NDA 017373	LIDEX (fluocinonide) Gel; Topical 0.05%	.....Do.
NDA 020073	ROMAZICON (flumazenil) Injectable; Injection, 1 mg/10 milliliters (mL) (0.1 mg/mL); 0.5 mg/5 mL (0.1 mg/mL).	Hoffmann-La Roche Inc., C/O Genentech Inc., 1 DNA Way, South San Francisco, CA 94080–4990.
NDA 020229	LEUSTATIN (cladribine) Injectable; Injection, 1 mg/mL	Janssen Pharmaceuticals Inc., C/O Johnson and Johnson Pharmaceutical Research and Development LLC, 920 Rt. 202 South, P.O. Box 300, Raritan, NJ 08869.
NDA 020347	HYTRIN (terazosin HCl) Capsule; Oral, EQ 1 mg Base; EQ 2 mg Base; EQ 5 mg Base; EQ 10 mg Base.	Abbott Laboratories Pharmaceutical Products Division, Dept. 491 AP6B 1, Abbott Park, IL 60064.
NDA 020560	FOSAMAX (alendronate sodium) Tablet; Oral, EQ 5 mg Base; EQ 10 mg Base; EQ 35 mg Base; EQ 40 mg Base.	Merck and Co. Inc., 126 East Lincoln Ave., RY 33 212, P.O. Box 2000, Rahway, NJ 07065–0900.
NDA 020813	KLONOPIN (clonazepam) Tablet, Orally Disintegrating Tablet (ODT); Oral, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg.	Hoffmann-La Roche Inc., 340 Kingsland St., Nutley, NJ 07110.
NDA 021046	CELEXA (citalopram hydrobromide) Solution; Oral, EQ 10 mg Base/5 mL.	Forest Laboratories Inc., Harborside Financial Center, Plaza V, Suite 1900, Jersey City, NJ 07311.
NDA 022246	METOZOLV ODT (metoclopramide HCl) Tablet, ODT; Oral, EQ 10 mg Base.	Salix Pharmaceuticals Inc., 8510 Colonnade Center Dr., Raleigh, NC 27615.
NDA 050533	VIBRA–TABS (doxycycline hyclate) Tablet; Oral, EQ 100 mg Base.	Pfizer Laboratories Inc., 235 East 42nd St., New York, NY 10017.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19272 Filed 8–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0092]

Guidance for Industry on Immunogenicity Assessment for Therapeutic Protein Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled ''Immunogenicity Assessment for Therapeutic Protein Products.'' Therapeutic protein products may elicit immune responses, which may lead to serious or life-threatening adverse events for the patient or loss of efficacy of the product. This guidance is intended to assist manufacturers and clinical investigators in developing a risk-based approach in both the nonclinical and clinical phases of product development that will allow them to evaluate and reduce the likelihood that the immunogenicity of the product will cause harm to patients. This guidance finalizes the draft guidance issued in February 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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 guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amy Rosenberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 2238, Silver Spring, MD 20892, 240–402–9789; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Rockville, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Immunogenicity Assessment for Therapeutic Protein Products.'' The purpose of this guidance is to assist

manufacturers and clinical investigators involved in the development of therapeutic protein products for human use in evaluating and reducing the risk of adverse events caused by immune responses to these products. The guidance: (1) Outlines and recommends adoption of a risk-based approach to evaluating and mitigating potential immune responses to therapeutic protein products that may affect their safety and efficacy, (2) describes various product- and patient-specific factors that affect the immunogenicity of or immune responses to therapeutic protein products and provides recommendations pertaining to each factor that may reduce the likelihood that an immune response will be generated to the product, (3) offers a series of recommendations for risk mitigation in the clinical phase of development of therapeutic protein products, (4) provides supplemental information on the diagnosis and management of particular adverse consequences of immune responses to therapeutic protein products, and (5) discusses briefly the use of animal studies and the conduct of comparative immunogenicity studies.

In the **Federal Register** of February 11, 2013 (78 FR 9702), FDA announced the availability of the draft guidance of the same title dated February 2013. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on immunogenicity assessments for therapeutic protein products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm; http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/Guidances/default.htm;* or *http://www.regulations.gov.*

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19267 Filed 8–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1108]

Revised Draft Guidance for Industry on Clinical Pharmacology Labeling for Human Prescription Drug and Biological Products—Considerations, Content, and Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Clinical Pharmacology Labeling for Human Prescription Drug and Biological Products—Considerations, Content, and Format.'' This draft guidance is one of a series of guidance documents intended to assist applicants in complying with FDA regulations on the content and format of labeling for human prescription drug and biological products. The guidance describes the recommended information to include in the *Clinical Pharmacology* section of labeling that pertains to the safe and effective use of human prescription drug and biological products. This revised draft guidance replaces the 2009 draft guidance for industry entitled ''Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.''

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 14, 2014.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 or 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. 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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lei Zhang, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3177, Silver Spring, MD 20993–0002, 301–796–5008 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' to revise the Agency's previous regulations on labeling (effective June 30, 2006). The final rule, commonly referred to as the Physician Labeling Rule (PLR), is designed to make information in prescription drug labeling easier for health care practitioners to access, read, and use, thereby increasing the extent to which practitioners rely on labeling for prescribing decisions. In the **Federal Register** of March 3, 2009 (74 FR 9250), FDA announced the availability of a draft guidance for industry entitled ''Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' as one of a series of guidance documents intended to assist applicants in complying with FDA regulations on the content and format of labeling for human prescription drug and biological