February 2012, Barr Pharmaceuticals added the following statement to the labeling directing health care professionals to transfer the capsule contents to a syringe that cannot accept a needle: ''A parenteral syringe can be used to extract the liquid inside the capsule, but the liquid should always be transferred to a syringe that cannot accept a needle and that is designed for administration orally or via a nasogastric tube or PEG.'' [6]

Despite these efforts by FDA and the drug's sponsor, a small number of adverse events due to erroneous intravenous administration continue to be reported to the Agency. Nevertheless, FDA believes that it is in the best interest of the public health for patients to continue to have access to this lifesaving drug for a number of reasons. First, only a portion of the patients treated with nimodipine capsules are unconscious and unable to swallow—these are the patients who are most vulnerable to the medication errors identified. Of those patients that begin their course of treatment (two capsules every 4 hours for 21 days) while unable to swallow, many improve to the point where they are awake and able to swallow a capsule soon after treatment begins. Hence, for many patients, the risk of erroneous intravenous administration is only present during a small percentage of their overall duration of treatment.

Second, we believe the approval of a nimodipine oral solution [7] that is administered via an oral syringe only will further prevent erroneous intravenous administration because it can be used for those patients who are unconscious or unable to swallow and eliminates the need for use of a parenteral syringe, which is the source of the medication errors. And third, we believe the capsules play an important role in treating patients with subarachnoid hemorrhage because many are discharged from the hospital while taking capsules, and capsules provide a more convenient route of administration that increases patient compliance.

As a result, we believe that the benefits of having nimodipine capsules on the market to treat these extremely sick patients, who could die or have serious permanent injury without treatment, outweigh the risks of medication errors.

Therefore, after considering the Petition and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that NIMOTOP (nimodipine) Capsules, 30 mg, was not withdrawn for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NIMOTOP (Nimodipine) Capsules, 30 mg, 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. FDA will not begin procedures to withdraw approval of the approved ANDAs that refer to NIMOTOP (Nimodipine) Capsules, 30 mg. Additional ANDAs that refer to NIMOTOP (Nimodipine) Capsules, 30 mg, may also 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: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07332 Filed 4–1–14; 8:45 am]

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PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.

[6] As used here, PEG refers to a percutaneous endoscopic gastrostomy tube.

[7] Nymalize was approved on May 10, 2013. See FDA's News Release, ''FDA Approves Nymalize—First Nimodipine Oral Solution for Use in Certain Brain Hemorrhage Patients,'' available at *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm352280.htm.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Guidance for Industry on Bioequivalence Recommendations for Specific Products; Availability,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

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 comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by June 2, 2014.

ADDRESSES: Submit written requests for single copies of the individual BE guidances 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. 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 recommendations.

Submit electronic comments on the draft product-specific BE recommendations 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: Kris André, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8866.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Guidance for Industry on Bioequivalence Recommendations for Specific Products; Availability,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that

process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received, and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on November 6, 2013 (78 FR 66745). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A	Amphotericin B.
	Atorvastatin calcium; Ezetimibe.
	Axitinib.
B	Brinzolamide.
	Buprenorphine.
	Buprenorphine hydrochloride.
	Buprenorphine hydrochloride; Naloxone hydrochloride.
C	Clobazam.
D	Desoximetasone (multiple reference listed drugs and dosage forms).
	Diazoxide.
E	Erythromycin.
	Estradiol.
F	Fentanyl citrate.
G	Guaifenesin.
H	Hydrochlorothiazide; Metoprolol succinate.
L	Levonorgestrel (multiple reference listed drugs).
	Linagliptin; Metformin hydrochloride.
M	Mesalamine.
P	Perampanel.
	Pindolol.
	Prednisolone acetate.
R	Rabeprazole sodium.
T	Teriflunomide.
	Tranylcypromine sulfate.
V	Verteporfin.

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A	Abiraterone acetate.
	Amlodipine besylate; Benazepril hydrochloride.
B	Brimonidine tartrate (multiple reference listed drugs).
D	Doxycycline hyclate.
	Dronabinol.
	Dutasteride; Tamsulosin hydrochloride.
I	Icosapent Ethyl.
L	Leuprolide acetate (multiple reference listed drugs and strengths).
M	Metoprolol succinate.
	Morphine sulfate.
	Mycophenolate mofetil (multiple reference listed drugs and dosage forms).
	Mycophenolic acid.
N	Naltrexone.
O	Octreotide acetate.
T	Trimethoprim.
	Triptorelin pamoate

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, please go to *http://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the Agency's current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do 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.

IV. Comments

Interested persons may submit either electronic comments on any of the specific BE recommendations posted on FDA's Web site to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessaary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and 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.*

V. Electronic Access

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

Dated: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07330 Filed 4–1–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0337]

Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format.'' This public workshop will provide a forum for discussing the development of these standards in the Drug Supply Chain Security Act of 2013. In particular, participants will be asked to provide information, current practices, research, and ideas on the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for each transfer of drug product in which a change of ownership occurs. This public workshop will also provide a forum to discuss the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey this information to the subsequent purchaser of a drug product and to facilitate the exchange of lot level data. As FDA continues to work on developing standards for interoperable exchange, the Agency is seeking public input to ensure that we consider information regarding all drug supply chain stakeholders.

DATES: The public workshop will be held on May 8 and 9, 2014, from 9 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave. Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993. Entrance for the public meeting