

employing modified release technologies, only immediate release formulations would be candidates for the in vitro BE assessment. For orally administered products, in vitro BE would be limited to disintegrated dosage forms. In cases when the administered drug acts both locally and systemically, blood level data may be used to confirm drug product BE of the systemic effects (and to confirm comparability of in vivo product disintegration in cases where multiple drugs are combined in a single solid oral dosage forms), while the additional in vitro dissolution data could be used to support the comparability of the local actions.

The in vitro BE approach should not be construed as a biowaiver, but rather as an alternative set of tests that would be handled in a manner consistent with that of an in vivo BE study. Specifically, (1) because an in vitro BE approach is not a biowaiver, sponsors would still need to meet the same environmental safety and human food safety requirements associated with products undergoing in vivo BE studies; (2) one in vitro study may not suffice when there are multiple product strengths (e.g., varying concentrations of an intramammary infusion); and (3) the in vitro method could be applied both to fully soluble and poorly soluble compounds. In vitro BE determinations would be based upon a battery of in vitro dissolution studies and physicochemical tests. Links to additional background material are provided on the Agency's Web site at: <http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm435459.htm>.

To assist FDA in developing guidance for demonstrating in vitro BE, with this notice the Agency is convening an open forum, providing a summary of what the Agency envisions as considerations pivotal to the BE assessment and inviting public comment on the various components of an in vitro BE determination.

## II. Participation in a Public Meeting

While oral presentations from specific individuals and organizations may be limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for the rulemaking. All relevant data and documentation should be submitted with the comments. Submit electronic comments 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. 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. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the rulemaking and will be accessible to the public at <http://www.regulations.gov>. The transcript of the proceedings from the public meeting will become part of the administrative record for the rulemaking. Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> under the docket number found in brackets in the heading of this document, and at FDA's Web site at <http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm435459.htm>. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Additionally, the public can access the meeting remotely by using the following Adobe Connect link: [https://collaboration.fda.gov/cvm\\_bioequivalence\\_meeting/](https://collaboration.fda.gov/cvm_bioequivalence_meeting/). The link will become active shortly before the meeting begins at 9 a.m. on April 16, 2015. Anyone interested in viewing the meeting remotely using this link will need to register as a guest using the registration information in this document. The Agency will be recording the meeting for subsequent viewing by the public. Once the recording has been made 508 compliant, it will be accessible at FDA's CVM Web site at <http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm435459.htm>.

Dated: March 12, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2014-0941]

### Port Access Route Study: In the Chukchi Sea, Bering Strait and Bering Sea

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice; withdrawal.

**SUMMARY:** The Coast Guard published a document in the **Federal Register** of February 19, 2015, (80 FR 8892) concerning the Port Access Route Study (PARS) in the Chukchi Sea, Bering Strait and Bering Sea. The February 19, 2015, PARS document was erroneously published and should be disregarded in its entirety.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice of study or any of the meetings, call or email LT Kody Stitz, Seventeenth Coast Guard District (dpw); telephone (907) 463-2270; email [Kody.J.Stitz@uscg.mil](mailto:Kody.J.Stitz@uscg.mil) or Mr. David Seris, Seventeenth Coast Guard District (dpw); telephone (907) 463-2267; email [David.M.Seris@uscg.mil](mailto:David.M.Seris@uscg.mil).

**SUPPLEMENTARY INFORMATION:** For correct information on the Port Access Route Study please see the Notice of Study published in the **Federal Register** on December 5, 2014 (79 FR 72157); and the Notice of Public Meetings published in the **Federal Register** on February 25, 2015 (80 FR 10137).

To electronically access all information referenced in this notice of correction visit <http://www.regulations.gov> and search for "USCG-2014-0941".

Dated: March 3, 2015.

**D.B. Abel,**

*Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.*

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