Certificate Expiration Date: May 31, 2020.

Model Number: HI–STORM 100.

* * * * *

Dated at Rockville, Maryland, this 29th day of November 2018.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2018–26878 Filed 12–11–18; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

RIN 2120–AK39

Notification of Replacement Public Meeting on Requirement for Helicopters To Use the New York North Shore Helicopter Route

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notification of public meeting.

SUMMARY: Due to inclement weather on November 15, 2018, the FAA announces a replacement public meeting to solicit feedback concerning the New York North Shore Helicopter Rule (''the Rule''). This meeting is being held pursuant to Section 182 of the FAA Reauthorization Act of 2018. The Rule requires civil helicopter pilots operating under Visual Flight Rules (VFR), whose route of flight takes them over the north shore of Long Island between the Visual Point Lloyd Harbor (VPLYD) waypoint and Orient Point (VPOLT), to use the North Shore Helicopter Route.

DATES: The public meeting will be held on Thursday, December 13, 2018.

ADDRESSES: The public meeting will be held at Vaugh College, 8601 23rd Avenue, Flushing NY 11369. The meeting is 7:00 p.m.–9:00 p.m. EST.

FOR FURTHER INFORMATION CONTACT: Christopher Bailey, Office of Rulemaking, Federal Aviation Administration; telephone (202) 267–4158; email *Christopher.Bailey@faa.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Public Meeting

The purpose of the public meeting is for the FAA to obtain feedback relevant to the Rule at subpart H of part 93, which requires civil helicopter pilots operating under VFR, whose route of flight takes them over the north shore of Long Island between the VPLYD waypoint and VPOLT, to use the North Shore Helicopter Route. The FAA will consider comments made at the public meeting in its review of the Rule.

Public Participation and Meeting Procedures

The meeting will use a workshop format. FAA will have several stations covering a number of relevant aspects of the Rule. Each station will be staffed by an FAA representative who is able to answer questions regarding that subject. There will also be a station where the public can submit a written statement or have their oral comment transcribed. No formal presentations will be made.

Section 182 of the FAA Reauthorization Act of 2018 also calls for a written comment period on the North Shore Helicopter Rule. See docket number FAA–2018–0954 to submit written comments.

Sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 3 calendar days before the meeting. The meeting will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate.

Issued in Washington, DC, on December 7, 2018.

Brandon Roberts,

Deputy Executive Director, Office of Rulemaking.

[FR Doc. 2018–26934 Filed 12–10–18; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA–2018–N–2732]

RIN 0910–AH57

Definition of the Term ''Biological Product''

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulation that defines ''biological product'' to incorporate changes made by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and to provide its interpretation of the statutory terms ''protein'' and ''chemically synthesized polypeptide.'' Under that interpretation, the term *protein* would mean any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. A *chemically synthesized polypeptide* would mean any alpha amino acid polymer that is made entirely by chemical synthesis and is greater than 40 amino acids but less than 100 amino acids in size. This proposed rule is intended to clarify the statutory framework under which such products are regulated.

DATES: Submit either electronic or written comments on the proposed rule by February 25, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 25, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 25, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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.