Requirements (CMR), Revision 01, dated August 28, 2017; or Airbus A310 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 01, dated August 28, 2017; as applicable. The initial compliance time for accomplishing the actions is at the applicable time specified in Airbus A300–600 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 01, dated August 28, 2017; or Airbus A310 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 01, dated August 28, 2017; as applicable; or within 90 days after the effective date of this AD; whichever occurs later.

(h) No Alternative Actions or Intervals

After accomplishment of the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals, may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

(i) Terminating Action

Accomplishing the actions required by paragraph (g) of this AD terminates all requirements of AD 2015–08–06.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0203, dated October 12, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0365.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on April 27, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–09981 Filed 5–11–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 343

[Docket No. FDA–1977–N–0025]

Partial Withdrawal of Proposed Amendment to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of partial withdrawal.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a partial withdrawal of a proposed rule published in the **Federal Register** of August 21, 2002 (2002 proposed rule). The proposed rule, if finalized, would have amended FDA's tentative final monograph (TFM) for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products to include ibuprofen as a generally recognized as safe and effective (GRASE) analgesic/antipyretic active ingredient for OTC use. FDA is withdrawing this proposed rule due to changes in our understanding of ibuprofen since FDA issued the proposed rule. FDA is not withdrawing those portions of the 2002 proposed rule to amend its regulations to include consistent pregnancy and allergy warnings for OTC IAAA drug products containing nonsteroidal anti-inflammatory active ingredients.

DATES: As of May 14, 2018, FDA withdraws the proposed additions to §§ 343.3 and 343.10, and proposed revisions to §§ 343.20 and 343.50 published on August 21, 2002 (67 FR 54139).

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kevin Lorick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5413, Silver Spring, MD 20993–0002, 301–796–6696, *Kevin.Lorick@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 16, 1988 (53 FR 46204), FDA published a proposed rule in the form of a TFM that proposed conditions under which OTC IAAA drug products would be generally recognized as safe and effective and not misbranded. On August 21, 2002 (67 FR 54139), FDA published a proposed rule that would have amended that TFM to include ibuprofen as a proposed GRASE analgesic/antipyretic active ingredient for OTC use. The 2002 proposed rule, if finalized, would have allowed manufacturers to market ibuprofen drug products for OTC use without submission of a new drug application (NDA), if all conditions of the monograph and other requirements were satisfied. At that time, ibuprofen drug products were marketed OTC under NDAs or abbreviated new drug applications (ANDAs) approved by FDA. This is still the case today—all ibuprofen drug products in the OTC marketplace are covered by NDAs or ANDAs. FDA is not aware of any ibuprofen drug products marketed under the TFM.

In the same 2002 proposed rule, the Agency proposed to update FDA regulations in 21 CFR part 201 to include consistent pregnancy and allergy warnings for OTC IAAA drug products containing nonsteroidal anti-inflammatory active ingredients. This proposal, if finalized, would update pregnancy, allergy, and asthma statements required in the labeling of certain IAAA products. FDA is not

withdrawing that part of the proposed rule.

On September 20, 2002, FDA held a meeting of the Nonprescription Drugs Advisory Committee to discuss safety issues related to the use of aspirin and other OTC nonsteroidal anti-inflammatory drugs (NSAIDs), including ibuprofen.[1] Safety issues discussed included stomach bleeding. As a result of this meeting and subsequent FDA review of the data and additional comments submitted to the public docket (see Docket No. FDA–1977–N–0025), all OTC ibuprofen products marketed under NDAs and ANDAs bear warnings about gastrointestinal bleeding. Warnings state that the risk of bleeding is higher in persons who are age 60 or older, have stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or nonprescription nonsteroidal anti-inflammatory drugs (NSAIDs), have three or more alcoholic drinks every day, or who take more or for a longer time than directed. These requirements are codified under 21 CFR 201.326(a)(2).

On February 10 and 11, 2014, FDA held a joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss cardiovascular safety issues related to the use of NSAIDS, including ibuprofen.[2] Safety issues included increased risk of heart attack and stroke that may be worsened with using too much NSAID or using NSAIDs for longer than recommended. Thus, FDA sent letters on August 18, 2016, to all manufacturers of ibuprofen requesting supplements to their applications to update labels with this new safety information. All OTC ibuprofen products now include label warnings against increased risk of heart attack and stroke with the use of NSAIDs other than aspirin.

To help ensure the continued utility of the consumer labeling as it relates to the safety of nonprescription ibuprofen drug products, FDA carefully monitors adverse event reporting.

The safety issues that have arisen subsequent to the 2002 proposed rule have caused the Agency to question whether ibuprofen can be ''generally recognized as safe and effective'' for use as an active ingredient in OTC IAAA drug products. For this reason, the Agency is withdrawing the 2002 proposed amendments to 21 CFR part 343. Our withdrawal of the 2002 proposed amendment to the IAAA TFM has no effect on the continued approval and marketing of the NDA and ANDA OTC ibuprofen drug products. As noted above, FDA has addressed the safety issues associated with ibuprofen through the NDA and ANDA safety framework, which is different from the safety framework for drugs marketed under the OTC monograph framework.

FDA is not withdrawing those portions of the 2002 proposed rule to amend its regulations to include consistent pregnancy and allergy warnings for OTC IAAA drug products containing nonsteroidal anti-inflammatory active ingredients.

II. Partial Withdrawal of the Proposed Rule

For the reasons described in this document, FDA is withdrawing portions of the 2002 proposed rule, which would have amended the OTC IAAA TFM.

Dated: May 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10194 Filed 5–11–18; 8:45 am]

BILLING CODE 4164–01–P

[1] *https://www.fda.gov/ohrms/dockets/ac/cder02.htm#NonprescriptionDrugs.*

[2] *https://wayback.archive-it.org/7993/20170404145443/https://www.fda.gov/AdvisoryCommittees/Calendar/ucm380871.htm.*

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0348]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone for certain navigable waters of the Lower Mississippi River. This action is necessary to provide for the safety of life on these navigable waters near New Orleans, LA, during a fireworks display on August 25, 2018. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector New Orleans or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 13, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0348 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Commander Benjamin Morgan, Sector New Orleans Waterways Management Division, U.S. Coast Guard; telephone 504–365–2231, email *Benjamin.P.Morgan@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector New Orleans
DHS Department of Homeland Security
FR Federal Register
MM Mile marker
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On April 9, 2018, AFX Pro, LLC, notified the Coast Guard that it would be conducting a fireworks display from 9 p.m. through 10 p.m. on August 25, 2018, for the National Guard Association of the United States Annual Conference. The fireworks will be launched from a barge in the Mississippi River at approximate mile marker (MM) 96.2 above Head of Passes, New Orleans, LA. Hazards from firework displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a one-mile stretch of the river.

The purpose of this rulemaking is to ensure the safety of vessels on the navigable waters within a one-mile stretch of the river before, during, and after the fireworks display. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a safety zone from 8:45 p.m. through 10 p.m. on August 25, 2018. The safety zone would cover all navigable waters of the Mississippi River above Head of Passes between mile markers (MM) 95.7 and 96.7. The duration of the zone is intended to ensure the safety of vessels