

Procedures (44 FR 11034, February 26, 1979).

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA-2016-9439; Directorate Identifier 2016-NM-170-AD.

(a) Comments Due Date

We must receive comments by January 30, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787-8 airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin B787-81205-SB240027-00, Issue 002, dated September 6, 2016.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical power.

(e) Unsafe Condition

This AD was prompted by a report indicating that during an airplane inspection in production, the variable frequency starter generator (VFSG) power feeder cables were found to contain terminal lugs incorrectly installed common to terminal blocks located in the wing front spar; the lugs were close to the structure causing the lug sleeve to come in contact with adjacent fasteners. We are issuing this AD to detect and correct incorrectly installed terminal lugs which may contact adjacent structure and be damaged. Damaged terminal lugs could cause electrical arcing in a flammable leakage zone which could result in an electrical short and the possible introduction of energy into the main fuel tanks.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection of Terminal Lugs and Corrective Actions

Within the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin B787-81205-SB240027-00, Issue 002, dated September 6, 2016: Do a general visual inspection of the right and left wing, section 16, VFSG power feeder cable terminal lugs at the terminal block for correct installation and do all applicable corrective actions in accordance with Boeing Alert Service Bulletin B787-81205-SB240027-00, Issue 002, dated September 6, 2016. Do all applicable corrective actions before further flight.

(h) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin B787-81205-SB240027-00, Issue 001, dated January 21, 2014.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), 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 manager of the ACO, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) 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.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Brendan Shanley, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW, Renton, WA 98057-3356; phone: 425-917-6492; fax: 425-917-6590; email: brendan.shanley@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110-SK57, Seal Beach, CA 90740-5600;

telephone: 562-797-1717; Internet: <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on December 1, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-29670 Filed 12-15-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2016-9435; Directorate Identifier 2016-NM-108-AD]

RIN 2120-AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2012-22-15 for all Fokker Services B.V. Model F28 Mark 0070 and Mark 0100 airplanes. AD 2012-22-15 currently requires revising the maintenance program to incorporate the limitations, tasks, thresholds, and intervals specified in certain revised Fokker maintenance review board (MRB) documents. Since we issued AD 2012-22-15, we received new revisions of airworthiness limitations items (ALI) documents, which introduce new and more restrictive maintenance requirements and airworthiness limitations. This proposed AD would require revising the maintenance or inspection program to incorporate new maintenance requirements and airworthiness limitations. We are proposing this AD to prevent the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by January 30, 2017.

ADDRESSES: You may send comments by any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Fax:** 202-493-2251.
- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone: +31 (0)88-6280-350; fax: +31 (0)88-6280-111; email: technicalservices@fokker.com; Internet <http://www.myfokkerfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-9435; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1137; fax 425-227-1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2016-9435; Directorate Identifier 2016-NM-108-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each

substantive verbal contact we receive about this proposed AD.

Discussion

On October 30, 2012, we issued AD 2012-22-15, Amendment 39-17252 (77 FR 68063, November 15, 2012) (“AD 2012-22-15”). AD 2012-22-15 requires actions intended to address an unsafe condition on all Fokker Services B.V. Model F28 Mark 0070 and Mark 0100 airplanes.

Since we issued AD 2012-22-15, we received Fokker Services Engineering Reports that consist of new and more restrictive airworthiness limitations (ALS).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive AD 2016-0125, dated June 21, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for all Fokker Services B.V. Model F28 Mark 0070 and Mark 0100 airplanes. The MCAI states:

Fokker Services recently published issue 15 of Engineering Report SE-623, containing Airworthiness Limitation Items (ALIs) and Safe Life Items (SLIs). This report is Part 2 of the Airworthiness Limitations Section (ALS Part 2) of the Instructions for Continued Airworthiness, referred to in Section 06, Appendix 1, of the Fokker 70/100 Maintenance Review Board document.

The complete ALS currently consists of:

Part 1—Report SE-473, Certification Maintenance Requirements (CMRs)—reference: EASA AD 2015-0027 [which corresponds to FAA AD 2016-11-22, Amendment 39-18549 (81 FR 36438, June 7, 2016)].

Part 2—Report SE-623, ALIs and SLIs—reference: EASA AD 2014-0224 [which corresponds to FAA AD 2012-22-15], and

Part 3—Report SE-672, Fuel ALIs and CDCCLS—reference: EASA AD 2015-0032 [which corresponds to FAA AD 2016-11-15, Amendment 39-18542 (81 FR 36447, June 7, 2016)].

The instructions contained in those reports have been identified as mandatory actions for continued airworthiness. Failure to accomplish these actions could result in an unsafe condition.

EASA previously issued AD 2014-0224, requiring the actions described in ALS Part 1 (report SE-473 issue 10), Part 2 (report SE-623 issue 13) and Part 3 (report SE-672 issue 4). Since that [EASA] AD was issued, ALS Part 1 was revised (SE-473 issue 11) and EASA issued AD 2015-0027 accordingly. ALS Part 3 was also revised (SE-672 issue 5) and EASA issued AD 2015-0032 accordingly.

For the reasons described above, this [EASA] AD retains part of the requirements of [EASA] AD 2014-0224, which is superseded, and requires implementation of the maintenance actions as specified in ALS Part 2 of the Instructions for Continued Airworthiness, Fokker Services Engineering

Report SE-623 at issue 15 (hereafter referred to as ‘ALS Part 2’ in this [EASA] AD).

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-9435.

Related Service Information Under 1 CFR Part 51

Fokker Services B.V. has issued Fokker Services B.V. Engineering Report SE-623, “Fokker 70/100 ALI’s and SLI’s,” Issue 16, issued June 3, 2016. The service information describes new and more restrictive maintenance requirements and airworthiness limitations. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (e.g., inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (m)(1) of this AD. The request should include a description of changes to the required inspections that will ensure the continued operational safety of the airplane.

Costs of Compliance

We estimate that this proposed AD affects 15 airplanes of U.S. registry.

The actions required by AD 2012-22-15, and retained in this proposed AD, take about 1 work-hour per product, at an average labor rate of \$85 per work-hour. Based on these figures, the estimated cost of the actions that are

required by AD 2012–22–15 is \$85 per product.

We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$1,275, or \$85 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2012–22–15, Amendment 39–17252 (77 FR 68063, November 15, 2012), and adding the following new AD:

Fokker Services B.V.: Docket No. FAA–2016–9435; Directorate Identifier 2016–NM–108–AD.

(a) Comments Due Date

We must receive comments by January 30, 2017.

(b) Affected ADs

- (1) This AD replaces AD 2012–22–15, Amendment 39–17252 (77 FR 68063, November 15, 2012) ("AD 2012–22–15").
- (2) This AD affects AD 2012–12–07, Amendment 39–17087 (77 FR 37788, June 25, 2012) ("AD 2012–12–07").
- (3) This AD affects AD 2008–06–20 R1, Amendment 39–16089 (74 FR 61018, November 23, 2009) ("AD 2008–06–20 R1").

(c) Applicability

This AD applies to Fokker Services B.V. Model F28 Mark 0070 and Mark 0100 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a revision of an airworthiness limitations items (ALI) document, which introduces new and more restrictive maintenance requirements and airworthiness limitations. We are issuing this AD to prevent reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Maintenance Program Revision, With Revised Compliance Language

This paragraph restates the requirements of paragraph (i) of AD 2012–22–15, with revised compliance language. Within 3 months after December 20, 2012 (the effective date of AD 2012–22–15), revise the maintenance program to incorporate the airworthiness limitations specified in Fokker Report SE–623, "Fokker 70/100 Airworthiness Limitation Items and Safe Life Items," Issue 13, released August 25, 2014 ("Fokker Report SE–623, Issue 13"). For all tasks and retirement lives identified in Fokker Report SE–623, Issue 13, the initial compliance

times start from the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD, and the repetitive inspections must be accomplished thereafter at the applicable interval specified in Fokker Report SE–623, Issue 13. Accomplishing the revision required by paragraph (k) of this AD terminates the requirements of this paragraph.

(1) Within 3 months after December 20, 2012 (the effective date of AD 2012–22–15).

(2) At the time specified in Fokker Report SE–623, Issue 13.

(h) Retained Corrective Actions, With Specific Delegation Approval Language

This paragraph restates the requirements of paragraph (j) of AD 2012–22–15, with specific delegation approval language. If any discrepancy, as defined in Fokker Report SE–623, Issue 13, is found during accomplishment of any task specified in Fokker Report SE–623, Issue 13: Within the applicable compliance time specified in Fokker Report SE–623, Issue 13, accomplish the applicable corrective actions in accordance with Fokker Report SE–623, Issue 13.

(1) If no compliance time is identified in Fokker Report SE–623, Issue 13, accomplish the applicable corrective actions before further flight.

(2) If any discrepancy is found and there is no corrective action specified in Fokker Report SE–623, Issue 13: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Fokker Services' EASA Design Organization Approval (DOA).

(i) Retained "No Alternative Actions or Intervals," With a New Exception

This paragraph restates the requirements of paragraph (k) of AD 2012–22–15, with a new exception. Except as required by paragraph (k) of this AD, after accomplishing 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 (m)(1) of this AD.

(j) Retained Method of Compliance With AD 2008–06–20, With Revised Compliance Language

This paragraph restates the requirements of paragraph (m) of AD 2012–22–15, with revised compliance language. Accomplishing the actions specified in paragraph (g) of this AD terminates the requirements of paragraphs (f)(1) through (f)(5) of AD 2008–06–20 R1.

(k) New Requirement of This AD: Maintenance or Inspection Program Revision

Within 30 days of the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate the ALI instructions specified in Fokker Services B.V. Engineering Report SE–623, "Fokker 70/100 ALI's and SLI's," Issue 16, issued June 3, 2016 ('Fokker Services B.V. Engineering

Report SE-623, Issue 16"). Accomplishing the revision required by this paragraph terminates the requirements of paragraph (g) of this AD. Accomplishing the revision required by this paragraph also terminates the requirements of paragraph (g) of AD 2012-12-07.

(1) The initial compliance times for the tasks specified in Fokker Services B.V. Engineering Report SE-623, Issue 16, are at the later of the applicable compliance times specified in Fokker Services B.V. Engineering Report SE-623, Issue 16, or within 30 days after the effective date of this AD, whichever is later.

(2) If any discrepancy is found, before further flight, repair using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the EASA; or Fokker B.V. Service's EASA DOA.

(l) No Alternative Actions or Intervals

After the maintenance or inspection program, as applicable, has been revised as required by paragraph (k) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless the actions or intervals are approved as an AMOC in accordance with the procedures specified in paragraph (m)(1) of this AD.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, Transport Airplane Directorate, 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 Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW, Renton, WA 98057-3356; telephone 425-227-1137; fax 425-227-1149. 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*: As of the effective date of this AD, 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 Branch, ANM-116, Transport Airplane Directorate, FAA; or EASA; or Fokker B.V. Services' EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2016-0125, dated June 21, 2016, for related information. You may examine the MCAI on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-9435.

(2) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone: +31 (0)88-6280-350; fax: +31 (0)88-6280-111; email: technicalservices@fokker.com; Internet <http://www.myfokkerfleet.com>. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on November 17, 2016.

Phil Forde,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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BILLING CODE 4910-13-P

date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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)*: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-3464 for "List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA-2016-N-3464]

RIN 0910-AH29

List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing a regulation to identify an initial list of bulk drug substances that can be used to compound drug products in accordance with certain compounding provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs. Specifically, the Agency proposes to place six bulk drug substances on the list. This proposed rule also identifies four bulk drug substances that FDA has considered and proposes not to include on the list. Additional substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of a future rulemaking.

DATES: Submit either electronic or written comments on the bulk drug substances list by March 16, 2017. See section VI for the proposed effective