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[FR Doc. 03-31992 Filed 12-29-03; 8:45 am]  
BILLING CODE 4810-33-C; 6210-01-C; 6714-01-C;  
6720-01-C; 7535-01-C; 6750-01-C; 6351-01-C; 8010-01-C

**DEPARTMENT OF TRANSPORTATION**  
**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. 2003-CE-39-AD]

RIN 2120-AA64

**Airworthiness Directives; GARMIN International Inc. GTX 330 Mode S Transponders and GTX 330D Diversity Mode S Transponders**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes to adopt a new airworthiness directive (AD) for certain GARMIN International Inc. GTX 330/GTX 330D Mode S transponders. This proposed AD would require you to install GTX 330/330D Software Upgrade Version 3.03. This proposed AD is the result of observations that the GTX 330 and GTX 330D may detect, from other aircraft, the S1 (suppression) interrogating pulse below the Minimum Trigger Level (MTL) and, in some circumstances, not reply. The GTX 330/330D should still reply even if it detects

S1 interrogating pulses below the MTL. We are issuing this proposed AD to prevent interrogating aircraft from possibly receiving inaccurate replies due to suppression from aircraft equipped with the GTX 330/330D Mode S Transponders when the pulses are below the MTL. The inaccurate replies could result in reduced vertical separation or unsafe TCAS resolution advisories.

**DATES:** We must receive any comments on this proposed AD by February 3, 2004.

**ADDRESSES:** Use one of the following to submit comments on this proposed AD:

- *By mail:* FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003-CE-39-AD, 901 Locust, Room 506, Kansas City, Missouri 64106.

- *By fax:* (816) 329-3771.

- *By e-mail:* 9-ACE-7-Docket@faa.gov.

Comments sent electronically must contain "Docket No. 2003-CE-39-AD" in the subject line. If you send comments electronically as attached electronic files, the files must be formatted in Microsoft Word 97 for Windows or ASCII.

You may get the service information identified in this proposed AD from GARMIN International Inc., 1200 East 151st Street, Olathe, KS 66062, 913-397-8200.

You may view the AD docket at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003-CE-39-AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Office hours are 8 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Roger A. Souter, FAA, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: 316-946-4134; facsimile: 316-946-4107; email address: roger.souter@faa.gov.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

*How Do I Comment on This Proposed AD?*

We invite you to submit any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES**. Include "AD Docket No. 2003-CE-39-AD" in the subject line of your comments. If you want us to acknowledge receipt of your mailed comments, send us a self-addressed, stamped postcard with the docket number written on it. We will date-stamp your postcard and mail it back to you.

*Are There Any Specific Portions of This Proposed AD I Should Pay Attention To?*

We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. If you contact us through a nonwritten communication and that contact relates to a substantive part of this proposed AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend this proposed AD in light of those comments and contacts.

**Discussion**

*What Events Have Caused This Proposed AD?*

The GTX 330/GTX 330D may detect from other aircraft the S1 (suppression) interrogating pulse below the MTL and, in some circumstances, does not reply. The GTX 330/330D should still reply even if it detects S1 interrogating pulses below the MTL. GARMIN International Inc. suspected the suppression problem after observation between GARMIN company aircraft that were equipped with the GTX 330 and Ryan Traffic and Collision Alert Device (TCAD). Engineering bench tests and test flights confirmed that this suppression problem existed.

*What Are The Consequences If the Condition Is Not Corrected?*

Interrogating aircraft could possibly receive inaccurate replies due to suppression from aircraft equipped with the GTX 330/330D Mode S Transponders when the pulses are below the MTL. The inaccurate replies could result in reduced vertical separation or unsafe TCAS resolution advisories.

*Is There Service Information That Applies To This Subject?*

GARMIN International Inc. has issued the Software Service Bulletin No.: 0304, Rev B, dated June 12, 2003.

*What Are the Provisions of This Service Information?*

The service bulletin includes:  
 —Modification instructions for upgrading to software version 3.03 and  
 —A listing of parts required to perform the modification.

**FAA's Determination and Requirements of This Proposed AD**

*What Has FAA Decided?*

We have evaluated all pertinent information and identified an unsafe

condition that is likely to exist or develop on other products of this same type design. Therefore, we are proposing AD action.

*What Would This Proposed AD Require?*

This proposed AD would require you to incorporate the actions in the previously-referenced service bulletin.

*How Does the Revision to 14 CFR Part 39 Affect This Proposed AD?*

On July 10, 2002, we published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

**Costs of Compliance**

*How Many Airplanes Would This Proposed AD Impact?*

We estimate that this proposed AD affects 1300 airplanes in the U.S. registry.

*What Would Be the Cost Impact of This Proposed AD on Owners/Operators of the Affected Airplanes?*

GARMIN International Inc. will cover all workhours and parts cost associated with this modification under warranty. The proposed AD would not impose any cost upon the owners/operators of any airplane that has the GTX 330/330D Software Upgrade to Version 3.03 installed.

**Compliance Time of This Proposed AD**

*What Would Be the Compliance Time of This Proposed AD?*

The compliance time of this proposed AD is within 30 days after the effective date of the AD.

*Why Is the Compliance Time Presented in Calendar Time Instead of Hours Time-In-Service (TIS)?*

The unsafe condition exists or could develop on airplanes equipped with the affected equipment regardless of airplane operation. For example, the unsafe condition has the same chance of occurring on an airplane with 50 hours TIS as it does on one with 5,000 hours TIS. Therefore, we are presenting the compliance time of the proposed AD in calendar time instead of hours TIS.

**Regulatory Findings**

*Would This Proposed AD Impact Various Entities?*

We have 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.

*Would This Proposed AD Involve a Significant Rule or Regulatory Action?*

For the reasons discussed above, I certify that this proposed AD:

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); and
3. 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.

We prepared a summary of the costs to comply with this proposed AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include "AD Docket No. 2003-CE-39-AD" in your request.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Safety.

**The Proposed Amendment**

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration 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):

**GARMIN International Inc.:** Docket No. 2003-CE-39-AD

*When Is the Last Date I Can Submit Comments on This Proposed AD?*

(a) We must receive comments on this proposed airworthiness directive (AD) by February 3, 2004.

*What Other ADs Are Affected By This Action?*

(b) None.

*What Products Are Affected by This AD?*

(c) This AD affects GARMIN International Inc. GTX 330/330D Mode S transponders that are installed on, but not limited to, the following airplanes, certificated in any category:

Manufacturer	Model
(1) Aermacchi S.p.A. ....	S.205-18/F, S.205-18/R, S.205-20/R, S.205-22/R, S208, S.208A, F.260, F.260B, F.260C, F.260D, F.260E, F.260F, S.211A.
(2) Aeronautica Macchi S.p.A. ....	AL 60, AL 60-B, AL 60-F5, AL 60-C5, AM-3.
(3) Aerostar Aircraft Corporation ....	PA-60-600 (Aerostar 600), PA-60-601 (Aerostar 601), PA-60-601P (Aerostar 601P), PA-60-602P (Aerostar 602P), PA-60-700P (Aerostar 700P), 360, 400.
(4) Alexandria Aircraft, LLC ....	14-19, 14-19-2, 14-19-3, 14-19-3A, 17-30, 17-31, 17-31TC, 17-30A, 17-31A, 17-31ATC.
(5) Alliance Aircraft Group LLC ....	15A, 20, H-250, H-295 (USAFU-10D), HT-295, H391 (USAFYL-24), H391B, H-395 (USAFU-28A or U-10B), H-395A, H-700, H-800, HST-550, HST-550A (USAF AU-24A), 500.
(6) American Champion Aircraft Corp. ....	402, 7GCA, 7GCB, 7KC, 7GCBA, 7GCAA, 7GCBC, 7KCAB, 8KCAB, 8GCBC.
(7) Sky International Inc. ....	A-1, A-1A, A-1B, S-1S, S-1T, S-2, S-2A, S-2S, S-2C.
(8) B-N Group Ltd. ....	BN-2, BN-2A, BN-2A-2, BN-2A-3, BN-2A-6, BN-2A-8, BN-2A-8, BN-2A-20, BN-2A-21, BN-2A-26, BN-2A-27, BN-2B-20, BN-2B-21, BN-2A-26, BN-2A-27, BN-2B-20, BN-2B-21, N-2B-26, BN-2B-27, BN-2T, BN-2T-4R, BN-2A MK.III, BN2A MK. III-2, BN2A MK. 111-3.
(9) Bellanca ....	14-13, 14-13-2, 14-13-3, 14-13-3W.
(10) Bombardier Inc. ....	(Otter) DHC-3, DHC-6-1, DHC-6-100, DHC-6-200, DHC-6-300.

Manufacturer	Model
(11) Cessna Aircraft .....	170, 170A, 170B, 172, 172A, 172B, 172C, 172D, 172E, 172F (USAF T-41A), 172G, 172H (USAF T041A), 172I, 172K, 172L, 172M, 172N, 172P, 172Q, 172R, 172S, 172RG, P172D, R172E (USAF T-41 B) (USAF T-41 C AND D), R172F (USAF T-41 D), R175G, R172H (USAF T-41 D), R172J, R172K, 175, 175A, 175B, 175C, 177, 177A, 177B, 177RG, 180, 180A, 180B, 180C, 180D, 180E, 180F, 180G, 180H, 180J, 180K, 182, 182A, 182B, 182C, 182D, 182E, 182F, 182G, 182H, 182J, 182K, 182L, 182M, 182N, 182P, 182Q, 182R, 182S, 182T, R182, T182, TR182, T182T, 185, 185A, 185B, 185C, 185D, 185E, A185E, A185F, 190, (LC-126A, B, C) 195, 195A, 195B, 210, 210A, 210B, 210C, 210D, 210E, 210F, T210F, 210G, T210G, 210H, T210H, 210J, T210J, 210K, T210K, 210L, T210L, 210M, T210M, 210N, P210N, T210N, 210R, P210R, T210R, 210-5 (205), 210-5A (205A), 206, P206, P206A, P206B, P206C, P206D, P206E, TP206A, TP206B, TP206C, TU206D, TU206E, TU206F, TU206G, 206H, T206H, 207, 207A, T207, T207A, 208, 208A, 208B, 310, 310A (USAF U-3A), 310B, 310C, 310D, 310E (USAF U-3B), 310F, 310G, 310H, E310H, 310I, 310J, 310J-1, E310J, 310K, 310L, 310N, 310P, T310P, 310Q, T310Q, 310R, T310R, 320, 320A, 320B, 320C, 320D, 320E, 320F, 320-1, 335, 340, 340A, 336, 337, 337A (USAF 02B), 337B, T337B, 337C, 337E, T337E, T337C, 337D, T337D, M337B (USAF 02A), 337F, T337F, T337G, 337G, 337H, P337H, T337H, T337H-SP, 401, 401A, 401B, 402, 402A, 402B, 402C, 411, 411A, 414, 414A, 421, 421A, 421B, 421C, 425, 404, 406, 441.
(12) Cirrus Design Corporation .....	SR20, SR22.
(13) Commander Aircraft Company .....	112, 112TC, 112B, 112TCA, 114, 114A, 114B, 114TC.
(14) de Havilland Inc. ....	DHC-2 Mk. I, DHC-2 Mk.II, DHC-2 Mk. III.
(15) Dynac Aerospace Corporation .....	(Voltaire) 10, (Voltaire) 10A, (Aero Commander) 100, (Aero Commander) 100A, (Aero Commander) 100-180.
(16) Diamond Aircraft Industries .....	DA-20 A1, DA20-C1, DA 40.
(17) Empresa Brasileira de Aeronautica S.A. EMBRAER .....	EMB-110P1, EMB-110P2.
(18) Extra Flugzeugbau GmbH .....	A300, EA300L, EA300S, EA300/200, EA-400.
(19) Fairchild Aircraft Corporation .....	SA26-T, SA26-AT, SA226-T, SA226-AT, SA226-T(B), SA227-AT, SA227-TT, SA226-TC, SA227-AC (C-26A), SA227-CC, SA227-DC (C-26B).
(20) Global Amphibians, LLC .....	Colonial C-1, Colonial C-2, Lake LA-4, Lake LA-4A, Lake LA-4P, Lake LA-4-200, Lake Model 250.
(21) Grob-Werke .....	G115, G115A, G115B, G115C, G115C2, G115D, G115D2, G115EG, G120A.
(22) Lancair Company .....	LC40-550FG.
(23) LanShe Aerospace, LLC .....	MAC-125C, MAC-145, MAC-145A, MAC-145B.
(24) Learjet Inc. ....	23.
(25) Lockheed Aircraft Corporation .....	18.
(26) Luscombe Aircraft Corporation .....	11A, 11E.
(27) Maule Aerospace Technology, Inc. ....	Bee Dee M-4, M-4, M-4C, M-4S, M-4T, M-4180C, M-4-180S, M-4-180T, M-4-210, M-4-210C, M-4-210S, M-4-210T, M-4-220, M-4-220S, M-4-220T, M-5-180C, M-5-200, M-5-210C, M-5-210TC, M-5-220C, M-5-235C, M-6-180, M-6-235, M-7-235, MX-7-235, MX-7-180, MX-7-420, MXT-7-180, MT-7-235, M-8-235, MX-7-160, MXT-7-160, MX-7-180A, MXT-7-180A, MX-7-180B, M-7-235B, M-7-235A, M-7-235C, MX-7-180C, M-7-260, MT-7-260, M-7-260C, M-7-420AC, MX-7-160C, MX-7-180AC, M-7-420A, MT-7-420.
(28) Mitsubishi Heavy Industries, Ltd .....	MU-2B-25, MU-2B-35, MU-2B-26, MU-2B-36, MU-2B-26A, MU-2B-36A, MU-2B-40, MU-2B-60, MU-2B, MU-2B-20, MU-2B-20, MU-2B-15.
(29) Mooney Airplane Company, Inc .....	M20, M20A, M20B, M20C, M20D, M20E, M20F, M20G, M20J, M20K, M20L, M20M, M20R, M20S, M22.
(30) Moravan a.s. ....	Z-242L, Z-143L.
(31) Navion Aircraft Company, Ltd. ....	NAVION, Navion (L-17A), Navion (L17B), Navion (L-17C), Navion B, Navion D, Navion E, Navion F, Navion G, Navion H.

Manufacturer	Model
(32) New Piper Aircraft, Inc .....	PA-12, PA-12S, PA-18, PA-18S, PA-18 "105" (Special), PA-18S "105" (Special), PA-18A, PA-18 "125" (Army L-21A), PA-18S "125," PA-18AS "125," PA-18 "135" (Army L-21B), PA-18A "135," PA-18S "135," PA-18 "150," PA-18A "150," PA-18S "150," PA-18AS "150," PA-19 (Army L-18B), PA-19S, PA-20, PA-20S, PA-20 "115," PA-20S "115," PA-20, "135," PA-20S "135," PA-22, PA-22-108, PA-22-135, PA-22S-135, PA-22-150, PA-22S-150, PA-22-160, PA-22S-160, PA-23, PA-23-160, PA-23-235, PA-23-250, PA-E23-250, PA-24, PA-24-250, PA-24-260, PA-24-400, PA-28-140, PA-28-150, PA-28-151, PA-28-160, PA-28-161, PA-28-180, PA-28-235, PA-28S-160, PA-28R-180, PA-28S-180, PA-28-181, PA-28R-200, PA-28R-201, PA-28R-201T, PA-28RT-201, PA-28RT-201T, PA-28-201T, PA-28-236, PA-30, PA-39, PA-40, PA-31P, PA-31T, PA-31T1, PA-31T2, PA-31T3, PA-31P-350, PA-32-260, PA-32-300, PA-32S-300, PA-32R-300, PA-32RT-300, PA-32RT-300T, PA-32R-301 (SP), PA-32R-301 (HP), PA-32R-301T, PA-32-301, PA-32-301T, PA-34-200, PA-34-200T, PA-34-220T, PA-42, PA-42-720, PA-42-1000, PA-42-720R, PA-44-180, PA-44-180T, PA-46-310P, PA-46-350P, PA-46-500TP
(33) Ostmecklenburgische Flugzeugbau GmGH .....	OMF-100-160.
(34) Piaggio Aero Industries S.p.A. ....	P-180.
(35) Pilatus Aircraft Ltd. ....	PILATUS PC-12, PILATUS PC-12/45, PC-6, PC-6-H1, PC-6-H2, PC-6/350, PC-6/350-H1, PC-6/350-H2, PC-6/A, PC-6/A-H1, PA-6/A-H2, PC-6/B-H2, PC-6/B1-H2, PC-6/B2-H2, PC-6/B2-H4, PC-6/C-H2, PC-6/C1-H2, PC-7.
(36) Prop-Jets, Inc. ....	200, 200A, 200B, 200C, 200D, 400.
(37) Panstwowe Zaklad Lotnicze (PZL) .....	PZL-104 WILGA 80, PZL-104M WILGA 2000, PZL-WARSZAWA, PZL-KOLIBER 150A, PZL-KOLIBER 160A.
(38) PZL WSK/Mielec Obrsk .....	PZL M20 03, PZL M26 01.
(39) Raytheon .....	35-33, 35-A33, 35-B33, 35-C33, 35-C33A, E33, E33A, E33C, F33, F33A, F33C, G33, H35, J35, K35, M35, N35, P35, S35, V35, V35A, V35B, 36, A36, A36TC, B36TC, 35, A35, B35, C35, D35, E35, F35, G35, 35R, F90, 76, 200, 200C, 200CT, 200T, A200, B200, B200C, B200CT, B200T, 300, 300LW, B300, B300C, 1900, 1900C, 1900D, A100-1 (U-21J), A200 (C-12A), A200 (C-12C), A200C (UC-12B), A200CT (C-12D), A200CT (FWC-12D), A200CT (RC-12D), A200CT (C-12F), A200CT (RC-12G), A200CT (RC-12H), A200CT (RC-12K), A200CT (RC-12P), A200CT (RC-12Q), B200C (C-12F), B200C (UC-12F), B200C (UC-12M), B200C (C-12R), 1900C (C-12J), 65, A65, A65-8200, 65-80, 65-A80, 65A80-8800, 65-B80, 65-88, 65-A90, 70, B90, C90, C90A, E90, H90, 65-A90-1, 65-A90-2, 65-A90-3, 65-A90-4, 95, B95, B95A, D95A, E95, 95-55, 95-A55, 95-B55, 95-B55A, 95-B55B (T-42A), 95-C55, 95-C55A, D55, D55A, E55, E55A, 56TC, A56TC, 58, 58A, 58P, 58PA, 58TC, 58TCA, 99, 99A, 99A (FACH), A99, A99A, B99, C99, 100, A100 (U-21F), A100A, A100C, B100, 2000, 3000, 390, 19A, B19, M19A, 23, A23, A23A, A23-19, A23-24, B23, C23, A24, A24R, B24R, C24R, 60, A60, B60, 18D, A18A, A18D, S18D, SA18A, SA18D, 3N, 3NM, 3TM, JRB-6, D18C, D18S, E18S, RC-45J (SNB-5P), E18S-9700, G18S, H18, C-45G, TC-45G, C-45H, TC-45H, TC-45J, UC-45J (SNB-5), 50 (L-23A), B50 (L-23B), C50, D50 (L-23E), D50A, D50B, D50C, D50E-5990, E50 (L-23D, RL-23D), F50, G50, H50, J50, 45 (YT-34), A45 (T-34A or B-45), D45 (T-34B).
(40) Rockwell International Corporation .....	BC-1A, AT-6 (SNJ-2), AT-6A (SNJ-3), AT-6B, AT-6C (SNJ-4), AT-6D (SNJ-5), AT-6F (SNF-6), SNJ-7, T-6G, NOMAD NA-260.
(41) Short Brothers & Harland Ltd. ....	SC-7 Series 2, SC-7 Series 3.
(42) Slingsby Aviation Ltd .....	T67M260, T67M260-T3A.
(43) SOCATA—Group Aerospatiale .....	TB9, TB10, TB20, TB21, TB200, TBM 700, M.S. 760, M.S. 760 A, M.S. 760 B, Rallye 100S, Rallye 150ST, Rallye 150T, Rallye 235E, Rallye 235C, MS 880B, MS 885, MS 894A, MS 893A, MS 892A-150, MS 892E-150, MS 893E, MS 894E, GA-7.
(44) Tiger Aircraft LLC .....	AA-1, AA-1A, AA-1B, AA-1C, AA-5, AA-5A, AA-5B, AG-5B.
(45) Twin Commander Aircraft Corporation .....	500, 500-A, 500-B, 500-U, 500-S, 520, 560, 560-A, 560-E, 560F, 680, 680E, 680F, 680FL, 680FL(P), 680T, 680V, 680W, 681, 685, 690, 690A, 690B, 690C, 690D, 695, 695A, 695B, 720, 700.
(46) Univair Aircraft Corporation .....	108, 108-1, 108-2, 108-3, 108-5.
(47) Vulcanair S.p.A. ....	P68, P68B, P68C, P68C-TC, P68 "Observer," P68 "Observer 2," P68TC "Observer," AP68TP300 "Spartacus," AP68TP 600 "Viator."
(48) Zenair Ltd. ....	CH2000.

*What Is the Unsafe Condition Presented in This AD?*

(d) The actions specified in this AD are intended to prevent interrogating aircraft from possibly receiving inaccurate replies,

due to suppression, from aircraft equipped with the GTX 330/330D Mode S Transponders when the pulses are below the Minimum Trigger Level (MTL). The inaccurate replies could result in reduced

vertical separation or unsafe TCAS resolution advisories.

*What Must I Do To Address This Problem?*

(e) To address this problem, you must accomplish the following:

Action	Compliance	Procedures
Install GTX 330/330D software upgrade to version 3.03.	Install the software upgrade within 30 days after the effective date of this AD, unless already accomplished.	Follow GARMIN International Inc. Service Bulletin No.: 0304, Rev B, dated June 12, 2003.

*How Do I Get Copies of the Documents Referenced in This AD?*

(g) You may get copies of the documents referenced in this AD from GARMIN International Inc. 1200 East 151st Street, Olathe, KS 66062. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on December 19, 2003.

**Michael Gallagher,**

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 03-31978 Filed 12-29-03; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 600

[Docket No. 2003N-0528]

#### Revision of the Requirements For Spore-Forming Microorganisms; Companion to Direct Final Rule

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. FDA is proposing this amendment due to advances in facility, system, and equipment design and in sterilization technologies that would allow work with spore-forming microorganisms to be performed in multiproduct manufacturing areas. We are amending the regulations because the existing requirement for always using separate, dedicated facilities and equipment for work with spore forming microorganisms is no longer necessary. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry

and to revise outdated regulations without diminishing public health protection. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. We are taking this action because the proposed changes are noncontroversial and we do not anticipate any significant adverse comments. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

**DATES:** Submit written comments on or before March 15, 2004.

**ADDRESSES:** Submit written or electronic comments on the proposed rule to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:**

Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion rule will also be considered as comments regarding the direct final rule. We are publishing the direct final rule because the rule contains noncontroversial changes, and we do not anticipate that it will receive any significant adverse comments.

An adverse comment is defined as a comment that explains why the rule

would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not subjects of significant adverse comments.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document, before the effective date of the direct final rule, confirming that the direct final rule will go into effect on June 1, 2004. Additional information about direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

Spore-forming microorganisms are used in the production of certain biological products. These microorganisms may be used as source material for further manufacture into final products used in the prevention, treatment or cure of a disease or condition of human beings. By their very nature, these microorganisms pose a great challenge to manufacturers. Bacteria produce spores as a means to survive adverse environmental