

therefore, (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This proposed rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would amend Class E airspace at Greenville Downtown Airport, Greenville, SC.

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1E, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, effective

September 15, 2014, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

ASO SC E5 Greenville, SC [Amended]

Greenville Downtown Airport, SC
(Lat. 34°50’53” N., long. 82°21’00” W.)
Greenville-Spartanburg International Airport, SC
(Lat. 34°53’44” N., long. 82°13’08” W.)
Donaldson Center Airport
(Lat. 34°45’30” N., long. 82°22’35” W.)
DYANA NDB
(Lat. 34°41’28” N., long. 82°26’37” W.)

That airspace extending upward from 700 feet above the surface within a 9.3-mile radius of Greenville Downtown Airport, and within a 10-mile radius of Greenville-Spartanburg International Airport, and within a 6.7-mile radius of Donaldson Center Airport, and within 4 miles northwest and 8 miles southeast of the 224° bearing from the DYANA NDB extending from the 6.7-mile radius to 16 miles southwest of Donaldson Center Airport.

Issued in College Park, Georgia, on March 30, 2015.

Gerald E. Lynch,

*Acting Manager, Operations Support Group,
Eastern Service Center, Air Traffic
Organization.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 320

[Docket No. FDA–2011–N–0830]

RIN 0910–AF97

Abbreviated New Drug Applications and 505(b)(2) Applications; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the proposed rule that appeared in the **Federal Register** of February 6, 2015. In the proposed rule, FDA requested comments on its proposal to implement portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which amended provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that govern the approval of 505(b)(2)

applications and abbreviated new drug applications (ANDAs). FDA also requested comment on its proposal to amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published February 6, 2015 (80 FR 6802). Submit either electronic or written comments on the proposed rule by June 8, 2015.

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

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2011–N–0830 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Janice L. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6268, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 6, 2015, FDA published a proposed rule with a 90-day comment period to

request comments on its proposal to implement portions of Title XI of the MMA, which amended provisions of the FD&C Act that govern the approval of 505(b)(2) applications and ANDAs. FDA also requested comment on its proposal to amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act. Comments on the proposed rule will inform FDA's rulemaking on ANDAs and 505(b)(2) applications.

The Agency has received requests for a 60-day extension of the comment period for the proposed rule. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 30 days, until June 8, 2015. The Agency believes that a 30-day extension of the comment period for the proposed rule allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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>.

Dated: April 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-09523 Filed 4-23-15; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-108214-15]

RIN 1545-BM69

Exception From Passive Income for Certain Foreign Insurance Companies

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance regarding when a foreign insurance company's income is excluded from the definition of passive income under section 1297(b)(2)(B). The proposed regulations affect the U.S. shareholders of foreign corporations. This document also invites comments from the public on all aspects of the proposed rules and provides the opportunity for the public to request a public hearing.

DATES: Written or electronic comments and requests for a public hearing must be received by July 23, 2015.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-108214-15), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-108214-15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-108214-15).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Josephine Firehock, (202) 317-4932; concerning submissions of comments or requests for a public hearing, Oluwafunmilayo (Funmi) Taylor at (202) 317-6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

The Department of Treasury (Treasury) and the IRS are aware of situations in which a hedge fund establishes a purported foreign reinsurance company in order to defer and reduce the tax that otherwise would be due with respect to investment income. Such foreign corporations may be Passive Foreign Investment Companies (PFICs). For a description of the recent trends and legislative proposals to address the issue, see "Background and Data with Respect to Hedge Fund Reinsurance Arrangements," JCT (July 31, 2014) (2014 JCT Report); see also Notice 2003-34, 2003-23 IRB 990 (May 9, 2003).

Under section 1297 of the Internal Revenue Code (Code), a foreign corporation is a PFIC if either 75 percent or more of its gross income for the taxable year is passive income ("passive income test"), or on average 50 percent or more of its assets produce passive income or are held for the production of passive income ("passive asset test"). Section 1297(b)(1) generally defines the

term "passive income" to mean any income of a kind that would be "foreign personal holding company income" as defined in section 954(c). In general, an asset is characterized as passive if it generates (or is reasonably expected to generate in the reasonably foreseeable future) passive income as defined in section 1297(b). Assets that generate both passive and non-passive income in a taxable year are treated as partly passive and partly non-passive assets in proportion to the relative amounts of income generated by those assets in that year. See Notice 88-22, 1988-1 CB 489 (February 26, 1988).

For purposes of applying the passive income test, section 1297(b)(2)(B) provides that, except as provided in regulations, the term "passive income" does not include any income that is derived in the active conduct of an insurance business by a corporation which is predominantly engaged in an insurance business and which would be subject to tax under subchapter L as an insurance company if the corporation were a domestic corporation. As the terms "active conduct" and "insurance business" are not defined in section 1297, Treasury and the IRS are proposing regulations to clarify the circumstances under which investment income earned by a foreign insurance company is derived in the active conduct of an insurance business for purposes of determining whether the income is passive income, and thus the extent to which the company's assets are treated as passive assets for purposes of determining whether the company is a PFIC.

The proposed regulations provide that the term "active conduct" has the same meaning as in § 1.367(a)-2T(b)(3), except that officers and employees are not considered to include the officers and employees of related entities. The proposed regulations define the term "insurance business" to mean the business activity of issuing insurance and annuity contracts and the reinsuring of risks underwritten by insurance companies, together with investment activities and administrative services that are required to support or are substantially related to insurance contracts issued or reinsured by the foreign insurance company.¹ The regulations also provide that an

¹ Cf. Committee on Ways and Means U.S. House of Representatives, Supplemental Report, The Deficit Reduction Act of 1984, 98th Cong. 2d Sess., H.R. Rept. 98-432, part 2, at 531 (Mar. 5, 1984); Committee on Finance United States Senate, The Deficit Reduction Act of 1984, S. Rept. 98-169, vol. 1, at 1407-08 (April 2, 1984); H.R. Rept. 98-861, 98th Cong. 2d Sess. at 1045 (June 23, 1984) (Conference Report).