

**§ 300.60 Waiver.**

(a) FDA may, at the request of an applicant or interested person or on its own initiative, grant a waiver of any of the requirements under § 300.53 with regard to a fixed-combination or co-packaged drug that is the subject of a pending application under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, or a combination of active ingredients under consideration for inclusion in an OTC monograph in accordance with part 330 of this chapter, if it finds one of the following:

(1)(i) There is a reasonable rationale for the combination of the individual active ingredients; and

(ii) Compliance with any of the requirements of § 300.53 would be infeasible or medically unreasonable or unethical; or

(2) The product contains all or a subset of the known components in the same ratio as a natural-source drug or a waived product provided the product is intended for the same conditions of use as the natural-source drug or the waived product; there is a reasonable basis to conclude that the product would provide a comparable clinical effect to the natural-source drug or the waived product; and, for products containing large molecules (macromolecules), the macromolecules have the same principal molecular structural features and overall mechanism of action as those in the natural-source drug or the waived product.

(b) If an applicant wishes to request a waiver, it must submit the waiver request with supporting documentation in an application under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act. If an interested person wishes to request a waiver, the waiver request must be submitted as part of a submission under part 330 of this chapter.

(c) FDA will provide appropriate written notice when the Agency grants a waiver on its own initiative, or grants or denies a request for a waiver. Fixed-combination and co-packaged drugs and combinations of active ingredients under consideration for inclusion in an OTC monograph for which a waiver is granted must still meet all other applicable requirements under section 505 of the Federal Food, Drug, and Cosmetic Act, section 351 of the Public Health Service Act, or § 330.10(a)(4) of this chapter, as appropriate.

**PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED**

■ 3. The authority citation for 21 CFR part 330 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 4. Amend § 330.10 by revising paragraph (a)(4)(iv) to read as follows:

**§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.**

\* \* \* \* \*

(a) \* \* \*

(4) \* \* \*

(iv) A combination of two or more active ingredients that are individually classified as drugs generally recognized as safe and effective in accordance with the requirements of § 300.53 of this chapter must meet the requirements of subpart B of part 300 of this chapter to be generally recognized as safe and effective and included in an OTC monograph. If such combination is granted a waiver under § 300.60 of this chapter, it must still meet all other applicable requirements of this subparagraph to be generally recognized as safe and effective and included in an OTC monograph. Unless otherwise specified in the applicable OTC monograph(s), combinations of active ingredients that are included in an OTC monograph may be used in either fixed-combination or co-packaged drugs.

\* \* \* \* \*

**PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS**

■ 5. The authority citation for 21 CFR part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 6. Amend § 610.17 by revising the section heading, designating the existing paragraph as paragraph (a), and by adding paragraph (b) to read as follows:

**§ 610.17 Permissible fixed-combinations.**

(a) \* \* \*

(b) A drug product subject to approval under section 351 of the Public Health Service Act may not be combined with another drug product except in accordance with subpart B of part 300 of this chapter.

Dated: December 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 1**

[REG–109822–15]

RIN 1545–BM70

**Country-by-Country Reporting**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document contains proposed regulations that would require annual country-by-country reporting by United States persons (U.S. persons) that are the ultimate parent entity of a multinational enterprise (MNE) group. These proposed regulations affect U.S. persons that are the ultimate parent entity of an MNE group that has annual revenue for the preceding annual accounting period of \$850,000,000 or more. This document 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 March 22, 2016.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG–109822–15), 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–109822–15), 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> (indicate IRS REG–109822–15).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Melinda E. Harvey, (202) 317–6934; concerning submissions of comments or requests for a public hearing, Oluwafunmilayo (Funmi) Taylor, (202) 317–6901 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

## Background

### 1. Objectives of Proposed Regulatory Action

Pursuant to the authority granted under sections 6001, 6011, 6012, 6031, 6038, and 7805, these proposed regulations describe a new requirement for certain U.S. persons that are the ultimate parent entity of an MNE group (U.S. MNE group) earning substantial annual revenue to file an annual report (U.S. CbC report) containing information on a country-by-country basis related to the MNE group's income and taxes paid, together with certain indicators of the location of economic activity within the MNE group. Because the reporting form is currently under development by the IRS and yet to be officially numbered, it is referred to in this preamble and the proposed regulations as Form XXXX, *Country-by-Country Report*. The categories of information required to be reported on the U.S. CbC report were developed in coordination with other member countries of the Group of Twenty (G20) and the Organisation for Economic Co-operation and Development (OECD). As discussed later in this preamble, the Treasury Department and the IRS have determined that the information required under these proposed regulations will assist in better enforcement of U.S. tax laws.

The G20 and OECD members, in coordination with other countries, developed a model template for the collection of country-by-country information from large MNE groups. The model template is intended to promote consistent and effective implementation of country-by-country reporting across tax jurisdictions (including countries and jurisdictions that are not countries but that have fiscal autonomy). The Treasury Department and the IRS anticipate that other tax jurisdictions will adopt information reporting requirements based on the model template that will mandate the filing of a country-by-country report (foreign CbC report) by MNE groups with an ultimate parent entity that is not a U.S. person (foreign MNE groups) that have substantial revenues. In developing these proposed regulations, the Treasury Department and the IRS determined that it is appropriate to use the model template as a guide because the model template was developed taking into account extensive consultations with stakeholders, including in particular U.S. MNE groups, in order to appropriately balance the benefits to tax administrations of collecting the information about an MNE group's

global operations against the compliance costs and burdens imposed on MNE groups. These consultations significantly affected both the scope of the information included in the model template as well as the flexibility afforded to MNE groups in determining how to compile that information in light of their different system capabilities. In addition, the model template reflects an agreed international standard for reporting by MNE groups that will promote consistency of reporting obligations across tax jurisdictions and reduce the risk that other countries will depart from the agreed standard by imposing inconsistent and overlapping reporting obligations on U.S. MNE groups. In this respect, the Treasury Department and the IRS note that clear and widely adopted documentation rules for MNE groups also help to reduce compliance costs. While the proposed regulations generally are consistent with the international standard, the proposed regulations also are tailored to be consistent with the preexisting information reporting requirements applicable to U.S. persons under sections 6001, 6011, 6012, 6031, and 6038.

The Treasury Department and the IRS have determined that the information required under these proposed regulations will assist in better enforcement of the federal income tax laws by providing the IRS with greater transparency regarding the operations and tax positions taken by U.S. MNE groups. In addition to this direct benefit expected from collecting U.S. CbC reports, as discussed in Part 2 of this preamble, pursuant to income tax conventions and other conventions and bilateral agreements relating to the exchange of tax information (collectively, information exchange agreements), a U.S. CbC report filed with the IRS may be exchanged by the United States with other tax jurisdictions in which the U.S. MNE group operates that have agreed to provide the IRS with foreign CbC reports filed in their jurisdiction by foreign MNE groups that have operations in the United States. Foreign CbC reports will provide the IRS with information that will assist the IRS in performing risk assessment of foreign MNE groups operating in the United States.

In particular, it is expected that CbC reports filed by both U.S. MNE groups and foreign MNE groups (collectively CbC reports) will help the IRS perform high-level transfer pricing risk identification and assessment. The information in a CbC report will not itself constitute conclusive evidence

that transfer pricing practices are or are not consistent with the arm's length standard. Accordingly, the information in a CbC report will not be used as a substitute for an appropriate transfer pricing determination based on a best method analysis (including a full comparability analysis of factors such as functions performed, resources employed, and risks assumed) as required by the arm's length standard set forth in the regulations under section 482, and transfer pricing adjustments will not be based solely on a CbC report. However, a CbC report may be used as the basis for making further inquiries into transfer pricing practices or other tax matters in the course of an examination of a member of an MNE group, and adjustments may be based on additional information developed through those inquiries in accordance with applicable law.

### 2. Exchange of Information, Confidentiality, and Improper Use of Information

Information reported pursuant to these proposed regulations is return information under section 6103. Section 6103 imposes strict confidentiality rules with respect to all return information. Moreover, section 6103(k)(4) allows the IRS to exchange return information with a competent authority of a tax jurisdiction only to the extent provided in, and subject to the terms and conditions of, an information exchange agreement. It is expected that the U.S. competent authority will enter into competent authority arrangements for the automatic exchange of CbC reports under the authority of information exchange agreements to which the United States is a party.

Consistent with established international standards, all of the information exchange agreements to which the United States is a party require the information exchanged to be treated as confidential by both parties, and disclosure and use of the information must be in accordance with the terms of the relevant information exchange agreement. Information exchange agreements generally prohibit the parties from using any information received for any purpose other than for the administration of taxes (*e.g.*, assessment or collection of, or enforcement or prosecution in respect of, the taxes covered by the information exchange agreement). Accordingly, under the terms of information exchange agreements, neither tax jurisdiction is permitted to disclose the information received under the information exchange agreement or use such information for any non-tax

purpose. Under the contemplated competent authority arrangements for the exchange of CbC reports, the competent authorities of the United States and other tax jurisdictions intend to further limit the permissible uses of exchanged CbC reports to assessing high-level transfer pricing and other tax risks and, where appropriate, for economic and statistical analysis.

Prior to entering into an information exchange agreement with another tax jurisdiction, the Treasury Department and the IRS closely review the tax jurisdiction's legal framework for maintaining confidentiality of taxpayer information and its track record of complying with that legal framework. In order to conclude an information exchange agreement with another tax jurisdiction, the Treasury Department and the IRS must be satisfied that the tax jurisdiction has the necessary legal safeguards in place to protect exchanged information, such protections are enforced, and adequate penalties apply to any breach of that confidentiality. Moreover, even when these conditions have been met and an information exchange agreement is in effect, the U.S. competent authority will not enter into a reciprocal automatic exchange of information relationship with a tax jurisdiction unless it has reviewed the tax jurisdiction's policies and procedures regarding confidentiality protections and has determined that such an exchange relationship is appropriate.

If the United States determines that a tax jurisdiction is not in compliance with confidentiality requirements, data safeguards, and the appropriate use standards provided for under the information exchange agreement or the competent authority arrangement, the United States will pause automatic exchange of CbC reports with that tax jurisdiction until such time as the United States is satisfied that the tax jurisdiction is meeting its obligations under the applicable information exchange or competent authority agreement or arrangement.

### Explanation of Provisions

#### 1. U.S. Persons Required To File Form XXXX, Country-by-Country Report

The proposed regulations generally require a U.S. business entity that is the ultimate parent entity of a U.S. MNE group to file Form XXXX, *Country-by-Country Report*. However, proposed § 1.6038-4(j) provides an exception from filing by a U.S. MNE group for an annual accounting period if the U.S. MNE group had revenues of less than \$850,000,000 for the preceding annual

accounting period. Generally, an ultimate parent entity of a U.S. MNE group is a U.S. business entity that controls a group of business entities, at least one of which is organized or tax resident outside of the United States, that are required to consolidate their accounts for financial reporting purposes under U.S. generally accepted accounting principles (GAAP), or that would be required to consolidate their accounts if equity interests in the U.S. business entity were publicly traded on a U.S. securities exchange. For purposes of the proposed regulations, the term business entity means a person as defined in section 7701(a) that is not an individual, as well as a permanent establishment that prepares financial statements separate from those of its owner for financial reporting, regulatory, tax reporting, or internal management control purposes.

Under proposed § 1.6038-4(b)(6), a business entity generally is considered resident in a tax jurisdiction if, under the laws of that tax jurisdiction, the business entity is liable to tax therein based on place of management, place of organization, or another similar criterion. However, a business entity will not be considered resident in a tax jurisdiction if it is liable to tax in such jurisdiction solely with respect to income from sources in such jurisdiction, or capital situated in such jurisdiction. The proposed regulations also provide rules for determining the tax jurisdiction of residence of a business entity that is resident in more than one tax jurisdiction or that is a permanent establishment.

Proposed § 1.6038-4(b)(4) defines a U.S. MNE group as a group of business entities, including the U.S. business entity that is the ultimate parent entity, that are required to consolidate their accounts under U.S. GAAP, or would be required to consolidate their accounts if equity interests in the ultimate parent entity were publicly traded on a U.S. securities exchange. Generally, under U.S. GAAP, if an entity owns a majority voting interest in another legal entity, the majority owner must combine the financial statements of the majority-owned entity with its own financial statements in consolidated financial statements. Financial Accounting Standards Board, *Accounting Standards Codification 810-10-15*,

“Consolidation—Overall—Scope and Scope Exceptions.” A U.S. MNE group does not include business entities that are accounted for under the equity method (because those entities do not consolidate their accounts with the equity owner), notwithstanding that the equity owner's proportionate share of

the business income of such entities is included in the equity owner's consolidated financial statements. The ultimate parent entity of a U.S. MNE group that is required to file Form XXXX, *Country-by-Country Report*, may be required to consolidate under U.S. GAAP one or more affiliated groups as defined in section 1504(a) that file a consolidated income tax return even though the ultimate parent entity is not an includible corporation as defined under section 1504(b) with respect to any of such consolidated groups. In such cases, the ultimate parent entity would report country-by-country information with respect to all such affiliated group entities (and any other business entities in the U.S. MNE group) on Form XXXX, *Country-by-Country Report*, and the parent corporations of the respective consolidated groups would not file a Form XXXX, *Country-by-Country Report*.

The Treasury Department and the IRS request comments on whether additional guidance is needed for determining which U.S. persons must file Form XXXX, *Country-by-Country Report*, or which entities are considered constituent entities of the filer. Specifically, the Treasury Department and the IRS request comments on whether additional guidance on the definition of U.S. MNE group is necessary to address situations where U.S. GAAP or regulations governing securities publicly traded on a U.S. securities exchange (U.S. securities regulations) permit or require consolidated financial accounting for reasons other than majority ownership and situations, if any, where U.S. GAAP or U.S. securities regulations permit separate financial accounting of majority-owned enterprises. Additionally, consideration has been given to the possible need for an exception to filing some or all of the information required on Form XXXX, *Country-by-Country Report*, for national security reasons. Requests by a U.S. person otherwise subject to the requirements to file Form XXXX, *Country-by-Country Report*, for an exception would require the Treasury Department and affected U.S. persons to coordinate with other federal agencies, such as the Department of Defense, to determine whether such an exception is warranted. The Treasury Department and the IRS request comments with respect to the procedures that a U.S. person should be required to follow in order to demonstrate a national security reason to receive an exception from filing some or all of the information

otherwise required by Form XXXX, *Country-by-Country Report*.

Generally, a constituent entity will have a tax jurisdiction of residence as determined under proposed § 1.6038–4(b)(6). However, a business entity that is treated as a partnership in the tax jurisdiction in which it is organized and that does not own or create a permanent establishment in another tax jurisdiction generally will have no tax jurisdiction of residence under the definition in proposed § 1.6038–4(b)(6) (other than for purposes of determining the ultimate parent entity of a U.S. MNE group). In these cases, it is expected that the partners will report their share of the partnership's items in the partners' respective tax jurisdictions of residence in order to determine the aggregate amounts reported on Form XXXX, *Country-by-Country Report*, regardless of whether the partnership has elected to be treated as an association for U.S. federal tax purposes. The Treasury Department and the IRS continue to consider whether a different rule is needed in the case of entities that are not treated as fiscally transparent in the owner or owners' tax jurisdiction(s) of residence but are treated as fiscally transparent in the entity's country of organization. The Treasury Department and the IRS request comments on the treatment of such entities in the CbC Report. In the case of a permanent establishment owned or created by a business entity that is treated as a partnership in the tax jurisdiction in which it is organized, the tax jurisdiction of residence of the permanent establishment for purposes of Form XXXX, *Country-by-Country Report*, is the location of the permanent establishment regardless of whether the permanent establishment is treated as a permanent establishment of the partnership or of the partners of the partnership by the tax jurisdiction in which the permanent establishment is located.

## 2. Information Required on Form XXXX, *Country-by-Country Report*

### A. Constituent Entity Information

Proposed § 1.6038–4(d)(1) describes the information that Form XXXX, *Country-by-Country Report*, may require with respect to each constituent entity of the U.S. MNE group. Generally, each business entity of a U.S. MNE group is considered a separate constituent entity of that U.S. MNE group; however, the term constituent entity does not include a foreign corporation or foreign partnership for which the ultimate parent entity is not required to furnish information under section 6038(a),

determined without regard to § 1.6038–2(j) and § 1.6038–3(c) (exceptions to information reporting for certain constructive owners and when more than one person otherwise would be required to submit the same information), or any permanent establishment of such foreign corporation or foreign partnership. For example, if none of the constituent entities owned by the ultimate parent entity directly, indirectly, or constructively owns enough stock in a foreign corporation to be considered a United States shareholder of a controlled foreign corporation, the foreign corporation is not a constituent entity. However, if the ultimate parent entity of a U.S. MNE group constructively owns more than 50 percent of the voting stock of a foreign corporation because a wholly-owned domestic subsidiary directly owns such stock and the domestic subsidiary reports information with respect to the foreign corporation pursuant to section 6038(a), the foreign corporation is a constituent entity of the U.S. MNE group notwithstanding that under § 1.6038–2(j)(2) the ultimate parent entity itself is not required to report information under section 6038(a). The IRS requests comments on whether additional guidance is needed regarding which business entities of a U.S. MNE group are considered constituent entities, particularly with respect to the exclusion of foreign corporations and partnerships for which an ultimate parent entity would not be required to furnish information under section 6038(a) without regard to §§ 1.6038–2(j) and 1.6038–3(c).

The information required with respect to each constituent entity includes identification of the tax jurisdiction, if any, in which the constituent entity is resident for tax purposes, the tax jurisdiction in which the constituent entity is organized or incorporated (if different from the tax jurisdiction of residence), and the main business activity or activities of the constituent entity. The tax identification number of each constituent entity used by the tax administration in its jurisdiction of tax residence also will be reported on Form XXXX, *Country-by-Country Report*.

### B. Financial and Employee Information

Proposed § 1.6038–4(d)(2) requires certain information to be reported for each tax jurisdiction in which one or more constituent entities of the MNE group is resident. The information for each tax jurisdiction must be presented on Form XXXX, *Country-by-Country Report*, as an aggregate of the requested information from all of the constituent

entities that are resident in the tax jurisdiction. In addition, proposed § 1.6038–4(d)(3)(i) provides that the information must be reported, in the aggregate, for any constituent entity or entities of a U.S. MNE group that have no tax jurisdiction of residence.

Specifically, the information required to be reported for each tax jurisdiction includes: (i) Revenues generated from transactions with other constituent entities of the U.S. MNE group; (ii) revenues not generated from transactions with other constituent entities of the U.S. MNE group; (iii) profit (or loss) before income tax; (iv) income tax paid on a cash basis to all tax jurisdictions, including any taxes withheld on payments received; (v) accrued tax expense recorded on taxable profits (or losses), reflecting only the operations in the relevant annual accounting period and excluding deferred taxes or provisions for uncertain tax positions; (vi) stated capital; (vii) accumulated earnings; (viii) number of employees on a full-time equivalent basis in the relevant tax jurisdiction; and (ix) net book value of tangible assets other than cash or cash equivalents.

The Treasury Department and the IRS have sought to minimize deviations from the model template that was developed by G20 and OECD member countries based on extensive consultations with stakeholders. Nonetheless, the Treasury Department and the IRS understand that there may be areas where further clarification or refinement is warranted to take into account the purpose of these proposed regulations to collect relevant information for high-level risk assessment while minimizing the burdens imposed. For example, the report seeks information on the taxes paid or accrued by MNE groups and their constituent entities on taxable income earned in the relevant accounting period. The Treasury Department and the IRS specifically solicit comments on the manner in which the proposed regulations request that information. The Treasury Department and the IRS also request comments on whether any of the other items should be further refined or whether additional guidance is needed with respect to how to determine any of the items in proposed § 1.6038–4(d)(2)(i)–(ix).

Proposed § 1.6038–4(d)(3)(iii) provides that the number of employees on a full-time equivalent basis may be determined as of the end of the accounting period, on the basis of average employment levels for the annual accounting period, or on any

other reasonable basis, and that independent contractors that participate in the ordinary operating activities of a constituent entity may be considered employees of such constituent entity for this purpose. The number of full-time equivalent employees in a tax jurisdiction of residence should be determined by reference to the employees that perform their activities for the U.S. MNE group within such tax jurisdiction of residence. U.S. MNE groups should use a reasonable basis to determine the tax jurisdiction of residence for which to report employees that perform activities for the U.S. MNE group in more than one tax jurisdiction or in a tax jurisdiction in which none of the constituent entities of the U.S. MNE group is resident. For example, a reasonable basis may be to report a travelling employee as part of the home office jurisdiction, as part of the tax jurisdiction in which the travelling employee spends the majority of his or her time, or as a fraction of one full-time equivalent employee in multiple tax jurisdictions based on the employee's time spent working in those jurisdictions. The Treasury Department and the IRS request comments on

whether guidance is needed regarding the treatment of other employment situations. The number of employees that a U.S. MNE group has in a particular tax jurisdiction should be determined on a consistent basis across entities, tax jurisdictions in which the U.S. MNE operates, and from year to year. It is not expected that the basis on which a U.S. MNE group determines the number of employees in a tax jurisdiction of residence will change from year to year. However, it is expected that Form XXXX, *Country-by-Country Report*, will provide a section for additional information that the ultimate parent entity of the U.S. MNE group will use to explain, among other things, any new approach adopted to determine the number of employees and why it was necessary or appropriate.

Proposed § 1.6038-4(e)(2) provides that the financial information reported on Form XXXX, *Country-by-Country Report*, may be based on certified financial statements, books and records maintained with respect to each constituent entity, or records used for tax reporting purposes. It is not necessary to reconcile the revenue, profit, and tax reported in the aggregate

or with respect to a specific tax jurisdiction on Form XXXX, *Country-by-Country Report*, to the consolidated financial statements of the U.S. MNE group or to the tax returns filed in any particular tax jurisdiction. Additionally, there is no need to make adjustments for differences in accounting principles applied from tax jurisdiction to tax jurisdiction. It is expected that Form XXXX, *Country-by-Country Report*, will include a section to provide additional information, including a brief description of the sources of data used in preparing the form, and, if a change is made in the source of data used from year to year, an explanation of the reasons for the change and its consequences. Permission to change the accounting principles, to make new or different adjustments for differences in accounting principles, or to change the source of data used in preparing Form XXXX, *Country-by-Country Report*, is not required.

#### C. Template for Form XXXX, Country-by-Country Report

The template on which Form XXXX, *Country-by-Country Report*, will be based is provided below.

		Name of the MNE group: Fiscal year concerned:															
Tax Jurisdiction	Constituent Entities resident in the Tax Jurisdiction	Tax Jurisdiction of organization or incorporation if different from Tax Jurisdiction of Residence	Main business activity(ies)														
			Research and Development	Holding or Managing intellectual property	Purchasing or Procurement	Manufacturing or Production	Sales, Marketing, or Distribution	Administrative, Management or Support Services	Provision of Services to unrelated parties	Internal Group Finance	Regulated Financial Services	Insurance	Holding shares or other equity instruments	Dormant	Other*		
	1.																
	2.																
	3.																
	1.																
	2.																
	3.																

\*Please specify the nature of the activity of the constituent entity in the "Additional Information" section.

		Name of the MNE group: Fiscal year concerned: Currency used:									
Tax Jurisdiction	Revenues			Profit (Loss) Before Income Tax	Income Tax Paid (on cash basis)	Income Tax Accrued – Current Year	Stated Capital	Accumulated Earnings	Number of Employees	Tangible Assets other than Cash and Cash Equivalents	
	Unrelated Party	Related Party	Total								

Name of the MNE group: Fiscal year concerned:
<b>Additional Information.</b> Please include any further brief information or explanation you consider necessary or that would facilitate the understanding of the compulsory information provided in the Country-by-Country Report.

3. Manner of Filing and Maintenance of Records for Form XXXX, Country-by-Country Report

Proposed § 1.6038–4(f) requires that Form XXXX, Country-by-Country Report, be filed with the ultimate parent entity’s timely-filed income tax return (with extensions). The proposed regulations do not require any U.S. business entity to provide notification that it is a constituent entity of a U.S. MNE group that is required to file a

Form XXXX, Country-by-Country Report.

While a U.S. business entity is not required to reconcile information reported on Form XXXX, Country-by-Country Report, with its financial statements or income tax returns, proposed § 1.6038–4(g) provides that a U.S. person required to file as an ultimate parent entity of a U.S. MNE group must maintain records to support the information provided on Form XXXX, Country-by-Country Report.

Proposed Effective/Applicability Date

These regulations are proposed to be applicable to taxable years of ultimate parent entities of US MNE groups that begin on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register** and that include annual accounting periods determined under section 6038(e)(4) of all foreign constituent entities and taxable years of all domestic constituent entities

beginning on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

### Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It also has been determined that section 553(b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

The IRS intends that the information collection requirements in these proposed regulations will be satisfied by submitting a new reporting form with an income tax return. The new reporting form has not yet been numbered and is referred to as Form XXXX, *Country-by-Country Report*, in this Preamble and the proposed regulations. For purposes of the Paperwork Reduction Act, the reporting burden associated with the collection of information in these proposed regulations will be reflected in the OMB Form 83–1, *Paperwork Reduction Act Submission*, associated with Form XXXX, *Country-by-Country Report*.

It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. chapter 6). Accordingly, a regulatory flexibility analysis is not required. This certification is based on the fact that these regulations will only affect U.S. corporations, partnerships, and trusts that have foreign operations when the combined annual revenue of the business entities owned by the U.S. person meets or exceeds \$850,000,000. Pursuant to section 7805(f), these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

### Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the “Addresses” heading. The Treasury Department and the IRS request comments on aspects of the proposed rules for which additional guidance is desired. All comments will be available at [www.regulations.gov](http://www.regulations.gov) or upon request. A public hearing will be

scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, then notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

### Drafting Information

The principal author of these proposed regulations is Melinda E. Harvey of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Department of the Treasury participated in their development.

### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

### Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

#### PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding the following entry in numerical order to read in part as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*  
\* \* \* \* \*

Section 1.6038–4 also issued under 26 U.S.C. 6038.

\* \* \* \* \*

■ **Par. 2.** Section 1.6038–4 is added to read as follows:

#### § 1.6038–4 Information returns required of certain United States persons with respect to such person’s U.S. multinational enterprise group.

(a) *Requirement of return.* Except as provided in paragraph (j) of this section, every United States person (U.S. person) that is an ultimate parent entity of a U.S. multinational enterprise (MNE) group as defined in paragraph (b)(1) of this section must make an annual return on Form XXXX, *Country-by-Country Report*, setting forth the information described in this section and any other information required by Form XXXX, *Country-by-Country Report*, with respect to each annual accounting period described in paragraph (c) of this section.

(b) *Definitions*—(1) *Ultimate parent entity of a U.S. MNE group.* An ultimate parent entity of a U.S. MNE group is a U.S. business entity that:

(i) Owns directly or indirectly a sufficient interest in one or more other business entities, at least one of which is organized or tax resident in a tax jurisdiction other than the United States, such that the U.S. business entity is required to consolidate the accounts

of the other business entities with its own accounts under U.S. generally accepted accounting principles, or would be so required if equity interests in the U.S. business entity were publicly traded on a U.S. securities exchange; and

(ii) Is not owned directly or indirectly by another business entity that consolidates the accounts of such U.S. business entity with its own accounts under generally accepted accounting principles in the other business entity’s tax jurisdiction of residence, or would be so required if equity interests in the other business entity were traded on a public securities exchange in its tax jurisdiction of residence.

(2) *Business entity.* For purposes of this section, a business entity is a person as defined in section 7701(a)(1) that is not an individual, and includes any entity that has a single owner and that is disregarded as a separate entity from its owner under § 301.7701–3 of this chapter. Also for purposes of this section, the term business entity includes a business establishment in a jurisdiction that is treated as a permanent establishment under an income tax convention to which that jurisdiction is a party or that would be treated as a permanent establishment under the Organisation for Economic Co-operation and Development (OECD) Model Tax Convention on Income and on Capital 2014 and that prepares financial statements separate from those of its owner for financial reporting, regulatory, tax reporting, or internal management control purposes.

(3) *U.S. business entity.* A U.S. business entity is a business entity that is organized or has its tax jurisdiction of residence in the United States.

(4) *U.S. MNE group.* A U.S. MNE group comprises the ultimate parent entity of a U.S. MNE group as defined in paragraph (b)(1) of this section and all of the business entities required to consolidate their accounts with the ultimate parent entity’s accounts under U.S. generally accepted accounting principles, or that would be so required if equity interests in the ultimate parent entity were publicly traded on a U.S. securities exchange, regardless of whether any such business entities could be excluded from consolidation solely on size or materiality grounds.

(5) *Constituent entity.* With respect to a U.S. MNE group, a constituent entity is any separate business entity of such U.S. MNE group, except that the term constituent entity does not include a foreign corporation or foreign partnership for which the ultimate parent entity is not required to furnish information under section 6038(a)

(determined without regard to § 1.6038–2(j) and § 1.6038–3(c)) or any permanent establishment of such foreign corporation or foreign partnership.

(6) *Tax jurisdiction of residence.* For purposes of this section, a tax jurisdiction is a country or a jurisdiction that is not a country but that has fiscal autonomy. A business entity is considered a resident in a tax jurisdiction if, under the laws of that tax jurisdiction, the business entity is liable to tax therein based on place of management, place of organization, or another similar criterion. However, a business entity will not be considered a resident in a tax jurisdiction if such business entity is liable to tax in such tax jurisdiction solely with respect to income from sources in such tax jurisdiction, or capital situated in such tax jurisdiction. If a business entity is resident in more than one tax jurisdiction, then the applicable income tax convention rules, if any, should be applied to determine the business entity's tax jurisdiction of residence. If a business entity is resident in more than one tax jurisdiction and no applicable income tax convention exists between those tax jurisdictions, or if the applicable income tax convention provides that the determination of residence is based on a determination by the competent authorities of the relevant tax jurisdictions and no such determination has been made, the business entity's tax jurisdiction of residence is the tax jurisdiction of the business entity's place of effective management determined in accordance with Article 4 of the OECD Model Tax Convention on Income and on Capital 2014. The tax jurisdiction of residence of a permanent establishment is the jurisdiction in which the permanent establishment is located. If a business entity does not have a tax jurisdiction of residence, then solely for purposes of paragraph (b)(1) of this section, the tax jurisdiction of residence is the business entity's country of organization.

(7) *Applicable financial statements.* An applicable financial statement is a certified audited financial statement that is accompanied by a report of an independent certified public accountant or similarly qualified independent professional that is used for purposes of reporting to shareholders, partners, or similar persons; for purposes of reporting to creditors in connection with securing or maintaining financing; or for any other substantial non-tax purpose.

(c) *Period covered by return.* The information required under paragraph (d) of this section with respect to a U.S. MNE group must be furnished for the

annual accounting period with respect to which the ultimate parent entity prepares its applicable financial statements ending with or within the ultimate parent entity's taxable year for which the Form XXXX, *Country-by-Country Report*, is filed. However, if the ultimate parent entity does not prepare applicable financial statements that consolidate the accounts of all constituent entities, the ultimate parent entity may provide the information required under paragraph (d) of this section based on applicable financial statements of constituent entities for their accounting period or periods that end with or within the ultimate parent entity's taxable year.

(d) *Contents of return—(1) Constituent entity information.* The return on Form XXXX, *Country-by-Country Report*, must contain so much of the following information with respect to each constituent entity, and in such form or manner, as the form prescribes:

- (i) The tax jurisdiction, if any, in which the constituent entity is resident for tax purposes;
- (ii) The tax jurisdiction in which the constituent entity is organized or incorporated (if different from the tax jurisdiction of residence);
- (iii) The tax identification number, if any, used for the constituent entity by the tax administration of the constituent entity's tax jurisdiction of residence; and
- (iv) The main business activity or activities of the constituent entity.

(2) *Tax jurisdiction of residence information.* The return on Form XXXX, *Country-by-Country Report*, will contain so much of the following information with respect to each tax jurisdiction in which one or more constituent entities of a U.S. MNE group is resident, and in such form or manner, as the form prescribes:

- (i) Revenues generated from transactions with other constituent entities;
- (ii) Revenues not generated from transactions with other constituent entities;
- (iii) Profit or loss before income tax;
- (iv) Total income tax paid on a cash basis to all tax jurisdictions, and any taxes withheld on payments received by the constituent entities;
- (v) Total accrued tax expense recorded on taxable profits or losses, reflecting only operations in the relevant annual accounting period and excluding deferred taxes or provisions for uncertain tax liabilities;
- (vi) Stated capital of all the constituent entities, except that the stated capital of a permanent

establishment must be reported by the legal entity of which it is a permanent establishment unless there is a defined capital requirement in the permanent establishment tax jurisdiction for regulatory purposes;

(vii) Total accumulated earnings, except that accumulated earnings of a permanent establishment must be reported by the legal entity of which it is a permanent establishment;

(viii) Total number of employees on a full-time equivalent basis in the relevant tax jurisdiction; and

(ix) Net book value of tangible assets other than cash or cash equivalents.

(3) *Special rules—(i) Constituent entity with no tax jurisdiction of residence.* The information listed in paragraph (d)(2) of this section also must be provided, in the aggregate, for any constituent entity or entities that have no tax jurisdiction of residence.

(ii) *Definition of revenue.* For purposes of this section, the term revenue includes all amounts of revenue, including revenue from sales of inventory and property, services, royalties, interest, and premiums. The term revenue does not include payments received from other constituent entities that are treated as dividends in the payor's tax jurisdiction of residence.

(iii) *Number of employees.* For purposes of this section, the number of employees on a full-time equivalent basis may be reported as of the end of the accounting period, on the basis of average employment levels for the annual accounting period, or on any other reasonable basis consistently applied across tax jurisdictions and from year to year. Independent contractors participating in the ordinary operating activities of a constituent entity may be reported as employees of such constituent entity. Reasonable rounding or approximation of the number of employees is permissible, provided that such rounding or approximation does not materially distort the relative distribution of employees across the various tax jurisdictions. Consistent approaches should be applied from year to year and across entities.

(iv) *Income tax paid and accrued tax expense of permanent establishment.* In the case of a constituent entity that is a permanent establishment, the amount of income tax paid and the amount of accrued tax expense referred to in paragraphs (d)(2)(iv) and (v) of this section should not include the income tax paid or tax expense accrued by the business entity of which the permanent establishment would be a part but for the second sentence of paragraph (b)(2)



of this section in that business entity's tax jurisdiction of residence on the income derived by the permanent establishment.

(v) *Certain transportation income.* If a constituent entity of a U.S. MNE group derives income from international transportation or transportation in inland waterways that is covered by income tax convention provisions that are specific to such income and under which the taxing rights on such income are allocated exclusively to one tax jurisdiction, then the U.S. MNE group should report the information required under paragraph (d)(2) of this section with respect to such income for the tax jurisdiction to which the relevant income tax convention provisions allocate these taxing rights.

(e) *Reporting of financial amounts.*—  
(1) *Reporting in U.S. dollars required.* All amounts furnished under paragraph (d)(2) of this section, other than paragraph (d)(2)(viii) of this section, must be expressed in U.S. dollars. If an exchange rate is used other than in accordance with U.S. generally accepted accounting principles for conversion to U.S. dollars, the exchange rate must be indicated.

(2) *Sources of financial amounts.* All amounts furnished under paragraph (d)(2) of this section, other than paragraph (d)(2)(viii) of this section, should be based on applicable financial statements, books and records maintained with respect to the constituent entity, or records used for tax reporting purposes.

(f) *Time and manner for filing.* Returns on Form XXXX, *Country-by-Country Report*, required under paragraph (a) of this section for a taxable year will be filed with the ultimate parent entity's income tax return for the taxable year on or before the due date (including extensions) for filing that person's income tax return.

(g) *Maintenance of records.* The U.S. person filing Form XXXX, *Country-by-Country Report*, as an ultimate parent entity of a U.S. MNE group must maintain records to support the information provided on Form XXXX, *Country-by-Country Report*. However, the U.S. person is not required to have or maintain records that reconcile the amounts provided on Form XXXX, *Country-by-Country Report*, with the tax returns of any tax jurisdiction or applicable financial statements.

(h) *Exceptions to furnishing information.* A U.S. person that is an ultimate parent entity of a U.S. MNE group is not required to report information under this section for an annual accounting period described in paragraph (c) of this section if the

annual revenue of the U.S. MNE group for the immediately preceding annual accounting period was less than \$850,000,000.

(j) *Effective/applicability dates.* The rules of this section apply to taxable years of ultimate parent entities of U.S. MNE groups that begin on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register** and that include annual accounting periods determined under section 6038(e)(4) of all foreign constituent entities and taxable years of all domestic constituent entities beginning on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

**John Dalrymple,**  
*Deputy Commissioner for Services and Enforcement.*

[FR Doc. 2015–32145 Filed 12–21–15; 4:15 pm]

**BILLING CODE 4830–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 171

[EPA–HQ–OPP–2011–0183; FRL–9940–59]

RIN 2070–AJ20

### Pesticides; Certification of Pesticide Applicators; Second Extension of the Comment Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** EPA issued a proposed rule in the **Federal Register** of August 24, 2015, concerning certification of applicators of restricted use pesticides. This document extends the comment period to January 22, 2016. The comment period is being extended to provide additional time for commenters to prepare their responses.

**DATES:** The comment period for the proposed rule published August 24, 2015, at 80 FR 51356, is extended. Comments, identified by docket identification (ID) number EPA–HQ–OPP–2011–0183, must be received on or before January 22, 2016.

**ADDRESSES:** Follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of August 24, 2015 (80 FR 51356) (FRL–9931–83).

**FOR FURTHER INFORMATION CONTACT:** Michelle Arling, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania

Ave. NW., Washington, DC 20460; telephone number: (703) 308–5891; email address: [arling.michelle@epa.gov](mailto:arling.michelle@epa.gov).

**SUPPLEMENTARY INFORMATION:** This document extends the public comment period established in the **Federal Register** document of November 18, 2015 (80 FR 72029) (FRL–9936–82), which extended the comment period originally set in the **Federal Register** document of August 24, 2015. In the November 18, 2015 document, comments were required to be submitted by December 23, 2015. EPA is hereby extending the comment period to January 22, 2016.

To submit comments, or access the docket, please follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of August 24, 2015. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### List of Subjects in 40 CFR Part 171

Environmental protection, Administrative practice and procedure, Certified applicator, Commercial applicator, Indian Country, Indian Tribes, Noncertified applicator, Pesticides and pests, Private applicator, Reporting and recordkeeping requirements, Restricted use pesticides.

Dated: December 21, 2015.

**Oscar Morales,**  
*Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2015–32457 Filed 12–22–15; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

#### 42 CFR Part 1001

### Solicitation of New Safe Harbors and Special Fraud Alerts

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice of intent to develop regulations.

**SUMMARY:** In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual document solicits proposals and recommendations for developing new, and modifying existing, safe harbor provisions under the Federal anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud Alerts.

**DATES:** To ensure consideration, public comments must be delivered to the