



ADMINISTRATOR

DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
WASHINGTON, D.C. 20220

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0294

The U.S. Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau (TTB), is taking this opportunity to respond to the request of the Food and Drug Administration (FDA) in FDA-2009-N-0294 for comments on the implementation of the Family Smoking Prevention and Tobacco Control Act ("the Act," Pub. L. 111-31), signed into law on June 22, 2009. The Act includes provisions that:

- require tobacco product manufacturers to register with the FDA;
- require, in some cases, FDA approval of new tobacco products before they enter the market;
- authorize the FDA to establish tobacco product standards;
- require the FDA to establish good manufacturing practices for tobacco product manufacturers; and
- authorize the FDA to prescribe recordkeeping requirements for countering the illicit trade of tobacco products.

TTB's role under the Internal Revenue Code of 1986 (IRC) in collecting the Federal excise tax on tobacco products, cigarette papers, and cigarette tubes and in the regulation of manufacturers and importers of those products in connection with the collection of these taxes includes some activities that are similar or parallel to the areas of responsibility of the FDA listed above. In addition, the Act contains several references to the Department of the Treasury or to TTB, including the following:

- Section 4 of the Act states that its provisions, which authorize the Secretary (that is, the Secretary of the Department of Health and Human Services (HHS)) to take certain actions with regard to tobacco products, shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986 (IRC);



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- Section 905 of the Federal Food, Drug, and Cosmetic Act was added by section 101 of the Act to provide that the Secretary of HHS shall consult with the Secretary of the Treasury in developing the forms to be used for registration to minimize the burden on those persons required to register with both the Secretary of HHS and the Tax and Trade Bureau of the Department of the Treasury; and
- Title III of the Act, Prevention of Illicit Trade in Tobacco Products, directs the Secretary of HHS to consult with the Attorney General and the Secretary of the Treasury in fulfilling its provisions.

We are providing these comments as a basis for appropriate further communication and consultation between the two agencies to assist the FDA in giving full effect to the provisions of the Act. We will also highlight specific areas in which TTB's experience with, and current activities in, the regulation of tobacco product manufacturers and importers might be relevant to the FDA in its new role.

TTB's Role

Tax Collection

The IRC imposes Federal excise taxes on tobacco products, cigarette papers, and cigarette tubes. For the purposes of tax administration, the IRC, either directly or through regulatory authority conferred on the Secretary of the Treasury, also imposes certain requirements on the manufacture, importation, and exportation of these products and also on the manufacture and importation of processed tobacco (upon which no Federal excise tax is imposed). (See 26 U.S.C. chapter 52 and 27 CFR parts 40, 41, 44, 45, and 46). TTB administers these statutory and regulatory provisions. Accordingly, with regard to tobacco products, TTB's mission under the IRC is to collect Federal excise taxes owed and to administer the related statutory and regulatory provisions to ensure protection of the revenue. In FY09 it is estimated that TTB will have collected approximately \$12 billion in Federal excise taxes on tobacco products and cigarette papers and tubes.

Tax Classification

There are six tobacco products defined under chapter 52 of the IRC. These are cigars, cigarettes, two types of smokeless tobacco (snuff and chewing tobacco), pipe tobacco, and roll-your-own tobacco. Each of these terms is also specifically defined in the IRC at 26 U.S.C. 5702, as shown below, as are the terms "cigarette paper," "cigarette tube," and "processed tobacco." Some of the definitions under the IRC include subjective criteria, such as whether a product is "likely to be offered to, or purchased by, consumers" as the defined tobacco product or for a specified use based on factors such as packaging and labeling.

Accordingly, in administering the Federal excise tax provisions, TTB evaluates products in order to determine whether the specific product under consideration

falls within one of the tobacco product definitions set forth in the IRC. Tax classification determinations are issued by the TTB Regulations and Rulings Division. These tax classification determinations are important for two reasons. First, not all products containing tobacco fall within the IRC excise tax regime. Second, each of the tobacco products defined in the IRC is subject to a different Federal excise tax rate and, for that reason, classification determinations have significant tax consequences. (Tax rates are set forth in 26 U.S.C. 5701).

Section 5702 of the IRC includes the following definitions:

- Tobacco products are cigars, cigarettes, smokeless tobacco, pipe tobacco, and roll-your-own tobacco. (26 U.S.C. 5702(c)).
- Smokeless tobacco is any snuff or chewing tobacco. (26 U.S.C. 5702(m)(1)).
- A cigar is “any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco” other than any roll of tobacco which is a cigarette within the meaning of cigarette set forth below. (26 U.S.C. 5702(a)).
- A cigarette is “(1) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and (2) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1).” (26 U.S.C. 5702(b)).
- Snuff is “any finely cut, ground, or powdered tobacco that is not intended to be smoked.” (26 U.S.C. 5702(m)(2)).
- Chewing tobacco is “any leaf tobacco that is not intended to be smoked.” (26 U.S.C. 5702(m)(3)).
- Pipe tobacco is “any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco to be smoked in a pipe.” (26 U.S.C. 5702(n)).
- Roll-your-own tobacco is “any tobacco, which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes or cigars, or for use as wrappers thereof.” (26 U.S.C. 5702(o)).

Under the IRC at 26 U.S.C. 5702(p) and the implementing regulations at 27 CFR 40.11, 41.11, and 44.11, processed tobacco is any tobacco that has undergone processing, but does not include tobacco products. The statutory definition further provides that the processing of tobacco does not include the farming or growing of tobacco or the handling of tobacco solely for sale, shipment, or delivery to a manufacturer of tobacco products or processed tobacco. Each definition in the regulations further states that the processing of tobacco does not include curing,

balancing, or packaging activities. In addition, the regulatory definitions provide that the processing of tobacco includes, but is not limited to, stemming (that is, removing the stem from the tobacco leaf), fermenting, threshing, cutting, or flavoring the tobacco, or otherwise combining the tobacco with non-tobacco ingredients.

It is important to note that some of the same terms used in the IRC and in the Act are defined by those statutes differently. The Act includes definitions of the terms "tobacco product", "cigarette", "cigarette tobacco", "little cigar", "roll-your-own tobacco", and "smokeless tobacco". Under the Act, a "tobacco product" is "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." (21 U.S.C. 321(rr)(1)). This definition appears to cover more products than is encompassed by the definition of "tobacco products" under the IRC and, for this reason, any data on "tobacco products" published by TTB might not be comparable to data compiled by the FDA based on the term "tobacco products" as defined in the Act.

The same result would be reached under the definition of "cigarette". Under the Act, the term "cigarette" in part follows the definition contained in the Federal Cigarette Labeling and Advertising Act (which conforms to the definition of "cigarette" in the IRC), but it also includes "tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco." (21 U.S.C. 387). The term "roll-your-own tobacco" is also defined differently in the Act. Under the Act, roll-your-own tobacco is "any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes." The definition in the IRC is broader in that it also includes tobacco for use in making cigars and for use as wrappers of cigars and cigarettes. As a result, the terms "cigarette" and "roll-your-own tobacco" in the Act and in the IRC are not comparable.

Along with the statutory definitions, TTB and its predecessor agency have also issued public guidance with regard to determining the appropriate classification of products such as cigars and cigarettes. For example, ATF Ruling 73-22, published in 1973, addressed the classification of cigar and cigarette products wrapped in a "substance containing tobacco," that is, reconstituted sheet tobacco. That ruling elaborated on the agency's position with regard to the wrapper material and the combination of other factors, such as packaging and labeling, that would be considered in determining whether a product wrapped in reconstituted sheet tobacco is a cigar or a cigarette.

TTB has also, in recent years, engaged in rulemaking with regard to classifying cigars and cigarettes for tax purposes. On October 25, 2006, TTB published in the

Federal Register (71 FR 62506) Notice No. 65, a notice of proposed rulemaking (NPRM) proposing objective standards for such determinations based on updated analytical procedures, including a standard for total reducing sugars (which encompasses all monosaccharides and disaccharides) in the filler tobacco of the product. Based on the comments received in response to that notice, TTB intends to publish in the near future a follow-up rulemaking document addressing how we intend to distinguish between the products for tax purposes.

TTB is also currently evaluating analytical methods for distinguishing between pipe tobacco and roll-your-own tobacco for tax purposes. This is in response to the enactment of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA, Public Law 111-3), effective April 1, 2009, which resulted in a significant tax difference between the two products.

Tax Administration — Permits, Records, Reports

Under chapter 52 of the IRC, those who are required to obtain a TTB permit before commencing operations are:

- Manufacturers of tobacco products or processed tobacco,
- Importers of tobacco products or processed tobacco, and
- Export warehouse proprietors.

Permits are issued by TTB's National Revenue Center in Cincinnati, Ohio. In this process, the NRC reviews permit applications and coordinates with TTB's Trade Investigation Division to determine whether an applicant qualifies for such permit. The NRC also processes tax returns, reports, and claims and is a primary source of technical assistance to industry members with regard to the forms and procedures required of TTB permittees.

Manufacturers of tobacco products or cigarette papers or tubes and export warehouse proprietors must file a bond that relates to the tax liability for the tobacco products on the premises covered by the permit. The amount of the bond is prescribed by regulation. (See 26 U.S.C. 5711). Manufacturers of processed tobacco and importers of processed tobacco or tobacco products are not required by TTB to obtain a bond – processed tobacco is not subject to Federal excise tax liability and the tax on imported tobacco products is paid to Customs and Border Protection (CBP), along with applicable duties, as part of the customs entry process.

In addition, manufacturers, importers, and export warehouse proprietors must make and keep the records and submit the reports prescribed by TTB regulations. The records that must be maintained include documenting the manufacture of tobacco products, the receipt of tobacco products (both in bond and taxpaid) and the circumstances of such receipt, the removal of tobacco products (both in bond

and upon payment of tax) and the circumstances of the removal, and losses and destruction of tobacco products after manufacture. Industry members are required to submit to TTB a monthly report of operations.

Tobacco product retailers, wholesalers, and distributors of tobacco products are not required under the IRC to obtain a TTB permit, and TTB does not regulate their activities (with some exceptions, such as collection of floor stocks tax when imposed by law). In addition, the TTB regulatory provisions apply only to those operating within the United States, and thus no permit is required of persons operating in a foreign country.

In contrast, as a result of the Act, new section 905 of the Federal Food, Drug, and Cosmetic Act requires annual registration by every person who owns or operates any establishment within any State or foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. Under the Act, such manufacture, preparation, compounding, or processing include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product packaging in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. In addition, under the Act, the FDA has new authority to require records for tracking and tracing, that is, for monitoring the movement of tobacco products from the point of manufacture through the products' distribution to retail outlets for purposes of assisting in the investigation of potential illicit trade, smuggling, or counterfeiting of tobacco products. This authority is set forth in new section 920(b)(1) of the Federal Food, Drug, and Cosmetic Act (as added by section 301 of the Act), which directs the FDA to promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products. This gives the FDA access to the records of a wider group than that covered under the IRC.

Again, it is important to note that the definitions of terms in the Act differ from those in the IRC. For example, chapter 52 of the IRC defines two types of "tobacco" manufacturers – a manufacturer of tobacco products (who is liable for the excise tax on such manufactured products) and a manufacturer of processed tobacco (who is not liable for excise tax, as processed tobacco is not subject to tax). The IRC also defines the term "importer" and "export warehouse proprietor", as these entities are required to obtain a permit from TTB before engaging in business. Section 5702 of the IRC includes the following definitions:

- A manufacturer of tobacco products is any person who manufactures cigars, cigarettes, smokeless tobacco, pipe tobacco, or roll-your-own tobacco but does not include a person who produces tobacco products solely for that person's own consumption or use; or a proprietor of a Customs bonded manufacturing warehouse with respect to the operation of such warehouse. (26 U.S.C. 5702(d)).

- A manufacturer of processed tobacco any person who processes any tobacco other than tobacco products. (26 U.S.C. 5702(p)).
- An export warehouse proprietor is any person who operates an export warehouse, and an export warehouse is a bonded internal revenue warehouse for the storage of tobacco products and cigarette papers and tubes and any processed tobacco, upon which the internal revenue tax has not been paid, for subsequent shipment to a foreign country, Puerto Rico, the Virgin Islands, or a possession of the United States, or for consumption beyond the jurisdiction of the internal revenue laws of the United States. (26 U.S.C. 5702(h) and (i)).

The Act defines two terms that share some elements of, but are otherwise markedly different from, the above IRC definitions, that is, “tobacco product manufacturer” and “tobacco warehouse”:

- A tobacco product manufacturer is any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States.
- A tobacco warehouse includes any person
 - who—
 - removes foreign material from tobacco leaf through nothing other than a mechanical process;
 - humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or
 - de-stems, dries, and packs tobacco leaf for storage and shipment;
 - who performs no other actions with respect to tobacco leaf; and
 - who provides to any manufacturer to whom the person sells tobacco all information related to the person’s actions described above that is necessary for compliance with this Act.

The term excludes any person who—

- reconstitutes tobacco leaf;
- is a manufacturer, distributor, or retailer of a tobacco product; or
- applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

The definition of the term “tobacco warehouse” shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this chapter of the actions described in such subparagraph is appropriate for the protection of the public health.

Thus, a “tobacco product manufacturer” under the Act is a much broader term than “a manufacturer of tobacco products” under the IRC, as under the Act importers

are considered manufacturers. Moreover, the definition of “manufacturer of processed tobacco” under the IRC and the definition of “tobacco warehouse” under the Act in part overlap but also differ significantly. For example, a person who de-stems tobacco would be considered a “manufacturer of processed tobacco” under the IRC and would also appear to be a “tobacco warehouse” under the Act. However, a person who applies chemical, additive, or other substances (other than potable water in the form of steam or mist) to the tobacco leaf would also be a “manufacturer of processed tobacco” under the IRC, while that person would not be a “tobacco warehouse” under the Act. We believe that a clear understanding of the differences between the IRC and the Act in these regards is important and underscores the need for adopting appropriate procedures for the sharing of information between the FDA and TTB and for the dissemination of information from the FDA and TTB to the affected industries and other members of the public.

Tax Administration — Package, Marks, Labels, and Notices

The IRC authorizes the Secretary of the Treasury to prescribe by regulation standards for packages, including marks, labels, and notices thereon, for tobacco products, processed tobacco, cigarette papers, and cigarette tubes. (See 26 U.S.C. 5723).

Packages

In general, under the TTB regulations, a package is defined as the immediate container in which tobacco products, processed tobacco, or cigarette papers or tubes are put up by the manufacturer or importer (in the latter case, at the time of release from customs custody) and offered for sale or delivery to the consumer. The size of a package may have a bearing on the taxable status of its contents. A container of processed tobacco, the contents of which weigh 10 pounds or less (including any added non-tobacco ingredients or constituents), that is removed from a factory or released from customs custody, is deemed to be a package offered for sale or delivery to the ultimate consumer, and therefore is a taxable commodity. The cellophane wrapping material is not considered to be part of the package of an export product. (See 27 CFR 40.11, 41.11, and 44.11).

The TTB regulations provide that, before removal (from the domestic factory or from customs custody) subject to tax, all tobacco products must be put up in packages that will securely contain the products and maintain any mark, label, or notice required by the regulations. The TTB regulations further provide that no package of tobacco products may contain with it, attached to it, or stamped, marked, written, or printed on it (1) any certificate, coupon, or other device purporting to be or to represent a ticket, chance, share, or an interest in, or dependent on, the event of a lottery, (2) any indecent or immoral picture, print, or representation, or (3) any statement or indication that United States tax has been paid. No person may purchase, receive, possess (except for personal

consumption), offer for sale, or sell or otherwise dispose of, after removal, any tobacco products that are not put up in packages bearing the marks, labels, and notices, as required under the TTB regulations. (See 27 CFR 40.211, 41.41, 44.181, 44.182, and 44.183, as well as, 26 U.S.C. 5751).

We note that the term “package” as set forth in the Act has a different meaning. The Act amends 21 U.S.C. 387 to define the term “package” to mean “a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers”.

Marks, Labels, and Notices

As noted above, under the IRC, all tobacco products, before removal subject to tax (that is, before removal from a manufacturer’s bonded premises or release from customs custody) must bear the marks, labels, and notices prescribed by the TTB regulations. Tobacco products manufactured in the United States for the domestic market must bear a mark identifying the manufacturer removing the product subject to tax (by name or TTB permit number) and the location (city and State) from which the products were removed subject to tax. A manufacturer may also comply with this requirement by obtaining TTB approval of an alternate method of marking in lieu of that prescribed. (See 27 CFR 40.212).

Under the TTB regulations, tobacco products for the domestic market, whether manufactured domestically or imported, must bear a notice providing information as to the tax classification and the taxable unit. These notices, which must be affixed or imprinted on the package prior to removal subject to tax, are as follows:

- Cigars. Packages must bear the designation “cigars”, the quantity of cigars contained in the package, and for small cigars, the classification of the product for tax purposes (either “small” or “little”). (See 27 CFR 40.214, 41.73, 44.186, and 45.44).
- Cigarettes. Packages must bear the designation “cigarettes”, the quantity of cigarettes contained in the package, and the classification for tax purposes (for small cigarettes, either “small” or “Class A”, and for large cigarettes, either “large” or “Class B”). (See 27 CFR 40.215, 41.74, and 45.45).
- Snuff. Packages must bear the designation “snuff” or “Tax Class M” and a clear statement of the actual pounds and ounces of the product contained in the package. As an alternative to the statement of weight appearing on the package, the shipping cases containing packages of snuff may bear a clear statement, in pounds and ounces, of the total weight of the product, the tax class of the product, and the total number of the packages of product contained in the shipping case. (See 27 CFR 40.216, 41.72, and 45.43).

- Chewing tobacco. Packages must bear the designation “chewing tobacco” or “Tax Class C” and a clear statement of the actual pounds and ounces of the product contained in the package. As an alternative to the statement of weight appearing on the package, the shipping cases containing packages of chewing tobacco may bear a clear statement, in pounds and ounces, of the total weight of the product, the tax class of the product, and the total number of the packages of product contained in the shipping case. (See 27 CFR 40.216, 41.72, and 45.43).
- Pipe tobacco. Packages must bear the designation “pipe tobacco” and a clear statement of the actual pounds and ounces of the product contained in the package. (See 27 CFR 40.216a, 40.216c, 41.72a, 41.72c, 45.45a, and 45.45c).
- Roll-your-own tobacco. Packages must bear the applicable designation “roll-your-own tobacco”, “cigarette tobacco”, “cigar tobacco”, “cigarette wrapper”, or “cigar wrapper”. The package must also bear a clear statement of the actual weight in pounds and ounces of the product in the package. (See 27 CFR 40.216b, 40.216c, 41.72b, 41.72c, 45.45b, and 45.45c).

Tobacco products for export must also bear, before removal, the words “Tax-exempt. For use outside U.S.” or “U.S. Tax-exempt. For use outside U.S.” except where a stamp, sticker, or notice, required by a foreign country or a possession of the United States, which identifies such country or possession, is imprinted on or affixed to the package. (See 27 CFR 44.185). We note, under the Act, the label, packaging, and shipping containers of tobacco products for introduction or delivery for introduction into interstate commerce in the United States must bear the statement “Sale only allowed in the United States.” (See new section 920(a)(1) of the Federal Food, Drug, and Cosmetic Act, as added by section 301 of the Act).

Repackaging of tobacco products after their removal subject to tax is strictly limited by the IRC and the TTB regulations.

As noted above, under the definitions of some tobacco products, the packaging and labeling of the product may affect the classification of the product under the IRC.

Comments with Regard to the General Categories Specified in FDA-2009-N-0294

Federal, State, and Local Government Collaboration

The Act, as noted above, specifically addresses collaboration and consultation with other agencies, including consulting with the Secretary of the Treasury in developing the forms to be used for registration of industry members and utilizing personnel, facilities, and other technical support available in other Federal

agencies to address tobacco product standards. In addition to areas specifically mentioned in the Act, there are other areas in which information sharing between TTB and the FDA could be productive. As described above, TTB already has authority and expertise over some of the entities and products over which the Act has given the FDA concurrent jurisdiction. TTB stands ready to work with the FDA with a view to ensuring that each agency will be able to fulfill its respective statutory mandate.

TTB also looks forward to participating in any interagency groups that may develop to effectively regulate tobacco products industry members while minimizing duplication of regulatory activity. We note that the Federal agencies that now share some regulatory or enforcement authority over aspects of the manufacture, importation, marketing, distribution, and sale of tobacco products include TTB, the FDA, the Federal Trade Commission (FTC), the U.S. Department of Agriculture (USDA) Farm Service Agency, CBP, Immigration and Customs Enforcement (ICE) and the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATFE). We believe that continued information sharing and other collaboration among these agencies, including technical support staff, will be critical to ensuring that each agency's mission goals will continue to be met in the most efficient and effective manner, minimizing redundancy where possible. TTB currently shares information, as appropriate, with the FDA (as regards alcohol beverage issues), USDA, CBP, and ATFE.

We note that TTB also has executed agreements for the sharing of tax information with 45 State revenue agencies and has, or is developing, memoranda of understanding (MOUs) with other Federal agencies. The formalization of information-sharing procedures between the agencies by means of an MOU or other agreement is critical for TTB because tax return information that TTB collects under the IRC, including the identity of industry members we regulate, is subject to strict disclosure rules under 26 U.S.C. 6103. While TTB may legally disclose such information to employees of other Federal agencies whose official duties require such inspection or disclosure, section 6103 imposes a number of disclosure safeguards that significantly restrict those agencies' subsequent use of that information.

Beyond our work with other Federal and State agencies, TTB also is a member of the U.S. delegation to the World Health Organization's Framework Convention on Tobacco Control.

In light of the close connection between FDA authority under the Act and TTB authority under the IRC as noted above, we look forward to exploring the possibility of formalizing an information-sharing understanding with the FDA that will meet the program needs of both agencies.

New Product Submission and Approval

The Act provides for premarket review by the Secretary of HHS of new tobacco products, which may entail determining what type of tobacco product it is and whether it is “substantially equivalent” to other tobacco products on the market. TTB similarly may evaluate a product containing tobacco for purposes of determining whether it falls within TTB’s jurisdiction and, if so, to ensure proper tax classification and collection under the IRC. Because some of the definitions of tobacco products under the Act and under the IRC contain subjective criteria and, as noted above, both similarities and differences, a determination made by the FDA under the Act could either parallel or differ from a classification determination made by TTB for Federal excise tax purposes. We believe that the two agencies should coordinate to ensure that tobacco product standards for the protection of public health under the Act and for proper tax classification and protection of the revenue under the IRC are harmonized to the greatest extent possible and, where they must differ, that the basis for the application of different standards is clear.

Enforcement

TTB employs a Tax Audit Division (TAD), a Trade Investigation Division (TID), and a Trade Analysis and Enforcement Division (TAED) as the principal means for enforcing the statutes and regulations under TTB’s jurisdiction. TAD is primarily responsible for auditing taxpayers to assess their compliance with the tax payment and related requirements under the IRC. TID conducts investigations of industry members’ operations to determine whether they are in compliance with the laws and regulations administered by TTB. TID also investigates applicants to determine whether they are qualified to obtain a TTB permit to engage in business activity regulated by TTB. TAED supports the work of TID and TAD in protecting the revenue and promoting voluntary compliance by monitoring the domestic trade in tobacco products.

Accordingly, with regard to the regulation of tobacco products and the manufacturers, importers, and export warehouses involved, TTB has personnel who, as part of their current duties and responsibilities, audit and investigate these operations. These routine duties may lead to, or be directed to, cases involving potential tax fraud, illicit trade, smuggling, and counterfeiting of tobacco products. TTB and its predecessor agencies have long been involved in these types of investigations.

With regard to the provisions of the Act concerning illicit trade, we note that the CHIPRA, referred to above, directed the Secretary of the Treasury to conduct a study of the magnitude of tobacco smuggling in the United States and submit to Congress recommendations for the most effective steps to reduce tobacco smuggling. The study is to include a review of the loss of Federal tax receipts due to illicit tobacco trade in the United States and the role of imported tobacco products in the illicit tobacco trade in the United States. As with all areas of

information described in this comment, TTB would welcome discussion and information sharing with the FDA in regard to these issues.

Research and Testing

TTB operates a Tobacco Laboratory, which provides technical support to other TTB offices by evaluating tobacco products for tax classification purposes and by developing analytical methods to support regulatory initiatives related to tax classification and to expand technical capabilities and expertise with regard to tobacco products. The Tobacco Laboratory also provides technical support to State tax authorities and other Federal agencies on tobacco-related issues. The Laboratory maintains professional relationships with other domestic and international members of the scientific community working with tobacco, including laboratories at USDA, the Centers for Disease Control, the Canada Border Services Agency, and the Tobacco Science Research Conference (TTB is an Analytical Methods Committee member). The TTB Tobacco Laboratory also participates in the World Health Organization Tobacco Laboratory Network (TobLabNet). TTB welcomes the opportunity to collaborate with the FDA on the sharing of scientific information.

Label Statements and Warnings

Under the Act a tobacco product will be deemed to be misbranded if, among other things, the package label does not contain the name and place of business of the tobacco product manufacturer, packer, or distributor and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

As noted above, the IRC at 26 U.S.C. 5723 authorizes the Secretary of the Treasury to prescribe by regulation requirements regarding tobacco product packages, marks, labels, and notices. These regulations require that the package (the immediate container) bear certain information identifying the manufacturer removing the product subject to tax. For purposes of collecting the Federal excise tax, the identity of the manufacturer liable for the tax, rather than the identity of a packer or distributor who is not the manufacturer, is the relevant information to be included on the label. Accordingly, the name and place of business of the packer or distributor might not satisfy the TTB regulatory requirements.

Also, with regard to the concept of a "packer", we note that the IRC at 26 U.S.C. 5751(a)(3) provides that no person shall, without intent to defraud the United States, purchase, receive, possess, offer for sale, or sell or otherwise dispose of, after removal, tobacco products that are put up in packages not bearing the marks, labels, and notices as required under section 5723. Similarly, 27 CFR 46.166 provides that tobacco products may be sold, or offered for sale, at retail from proper packages bearing the mark and notice prescribed in 27 CFR parts 40 and 41, provided the products remain in the packages until removed by the customer or in the presence of the customer. Accordingly, except under very limited

circumstances, tobacco products must remain in the packages in which they were placed by the manufacturer upon their removal subject to tax, until removed from the packages by the consumer or in the presence of the consumer, and those packages must bear the marks, labels, and notices, required by law and regulation, indicating the manufacturer who paid the tax on the products and other tax-related information. To the extent that a "manufacturer" is not the same as a "packer" under the Act, there is a potential for inconsistency as regards tobacco product labeling under the Act and the IRC.

TTB is also concerned that any "pre-market approval" of tobacco product packages, labels, and label information by the Secretary of HHS may conflict with the information required for administering the Federal excise tax provisions, particularly information that may affect a product's tax classification under the IRC. We are also concerned that the regulated entities may assume that approval of labels by HHS/FDA means that the labels comply with all Federal requirements, even though the TTB regulatory requirements necessary for implementation of the Federal excise tax may not have been met. TTB looks forward to further consultation with the FDA with regard to these issues.

Tobacco Product Standards

TTB's role with regard to tobacco products classification, and the similarities and differences between the tobacco product definitions under the Act and the IRC, have been discussed above.

Manufacturing Restrictions and Facilities Controls

TTB's role with regard to regulating the operations of manufacturers, importers, and export warehouse proprietors has been discussed above.

Conclusion

We are grateful for the opportunity to describe TTB's statutory and regulatory role in regard to tobacco products, and we look forward to continued collaboration with the FDA with a view to ensuring the greatest possible harmonization between our respective statutory mandates.

Respectfully submitted,



John J. Manfreda
Administrator