A false positive test result for an individual may lead to inappropriate use of antibiotics for treatment.

The FDA document entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of Clostridium difficile,” which addresses this risk through:
- Specific Device Description Requirements.
- Performance Studies.
TABLE 1—IDENTIFIED RISKS AND REQUIRED MITIGATIONS—Continued

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Required mitigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>A false negative test result for an individual may lead to a potential delay in</td>
<td>The FDA document entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of Clostridium difficile,” which addresses this risk through:</td>
</tr>
<tr>
<td>Failure of the test to be used or perform properly</td>
<td>The FDA document entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of Clostridium difficile,” which addresses this risk through:</td>
</tr>
<tr>
<td></td>
<td>Labeling.</td>
</tr>
<tr>
<td>Failure to properly interpret the test results</td>
<td>The FDA document entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of Clostridium difficile,” which addresses this risk through:</td>
</tr>
<tr>
<td></td>
<td>Labeling.</td>
</tr>
</tbody>
</table>

FDA believes that the measures set forth in the special controls guideline entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of Clostridium difficile” are necessary, in addition to general controls, to mitigate the risks to health described in table 1.

A. difficile toxin gene amplification assay is a prescription device. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the C. difficile toxin gene amplification assay they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:


2. Add §866.3130 to subpart D to read as follows:

   §866.3130 Clostridium difficile toxin gene amplification assay.

   (a) Identification. A Clostridium difficile toxin gene amplification assay is a device that consists of reagents for the amplification and detection of target sequences in Clostridium difficile toxin genes in fecal specimens from patients suspected of having Clostridium difficile infection (CDI). The detection of clostridial toxin genes, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of CDI caused by Clostridium difficile.

   (b) Classification. Class II (special controls). The special controls are set forth in FDA’s guideline document entitled: “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of Clostridium difficile: Guideline for Industry and Food and Drug Administration Staff.” See §866.1(e) for information on obtaining this document.

   Dated: August 21, 2015.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2015–21237 Filed 8–26–15; 8:45 am]
BILLING CODE 4166–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9731]

RIN 1545–BM11

Allocation of W–2 Wages in a Short Taxable Year and in an Acquisition or Disposition

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations relating to the allocation of W–2 wages for purposes of the W–2 wage limitation on the amount of a taxpayer’s deduction related to domestic production activities. Specifically, the temporary regulations provide guidance on: the allocation of W–2 wages paid by two or more taxpayers that are employers of the same employees during a calendar year; and the determination of W–2 wages if the taxpayer has a short taxable year. The text of the temporary regulations