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Proposed Rule for Post-marketing Safety Reporting of Combination Products

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If you or someone you know uses a combination product to treat an illness or medical condition, you can sleep better tonight. But, if your company markets a combination product in the United States, you may want to read on. The reporting of safety issues related to these products is going to become more thorough and clear-cut.

The FDA plans to plug a very large hole in the regulation of combination products – those that govern products formed from any combination of drugs, devices, or biological products. Current combination product rules fail to describe clear and concrete standards and timeframes for reporting post-marketing safety issues to the FDA.

The Proposed Rule, “Postmarketing Safety Reporting for Combination Products” will create 21 CFR Part 4, Subpart B.[1] The proposed rule is important because the safety reporting process for a combination product is governed by one of three sets of reporting provisions: 21 CFR Parts 310 and 314 for drugs; Parts 600 and 606 for biological products; and Part 803 for medical devices.

Currently, manufacturers of combination products must report safety issues to the FDA by following the regulations for the product component, under which the product was approved for marketing. For example, if a combination product was approved and marketed under an NDA, safety reporting follows the requirements of 21 CFR Part 314. However, this safety reporting method does not accommodate the unique safety reporting provisions for all product components, and could lead to a loss of information needed by the FDA to protect public health.

The proposed rule will remedy this potential loss of valuable safety information by requiring that reporters of postmarketing safety issues continue “. . . to comply with the requirements associated with the application used to approve or clear the combination product, as long as there is compliance, as appropriate, with the five unique provisions.”[2]

In the “Description of the Proposed Rule” the five unique provisions are clearly explained, and examples are provided (see the **Proposed Rule** for detail).[3] Once the proposed rule becomes effective (comments are due by December 30, 2009), combination product manufacturers will be required to provide more consistent and complete safety reports, and the FDA will have more information on combination products, upon which to make sound regulatory decisions about product safety and public health. In this era of rapidly developing medical technologies, this long-anticipated rule is making progress.

Sources:

[1] Federal Register/Vol. 74, No. 189/Thursday, October 1, 2009/Proposed Rules, pp. 50744-50758.

[2] Federal Register/Vol. 74, No. 189/Thursday, October 1, 2009/Proposed Rules, pp. 50750.

[3] <http://edocket.access.gpo.gov/2009/pdf/E9-23519.pdf>