

## E-ALERT | Food & Drug

March 9, 2011

### SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

#### FEBRUARY 2011

This e-alert is part of a monthly series of e-alerts summarizing publicly-available FDA enforcement letters (i.e., warning letters and untitled letters) relating to the advertising and promotion of drugs, biologics, and medical devices. In February 2011, the Office of Compliance and Biologics Quality (OCBQ) in FDA's Center for Biologics Evaluation and Research (CBER) posted the following letter on its website:<sup>1</sup>

- Untitled letter to Novartis Vaccines and Diagnostics, Inc. re: FLUVIRIN® [Influenza Virus Vaccine] (February 4, 2011) ("Novartis Untitled Letter")<sup>2</sup>

The Office of Compliance in FDA's Center for Devices and Radiological Health (CDRH) posted the following letter on the FDA warning letter website:

- Warning letter to STERIS Corporation re: Verify SixCess Class 6 Challenge Packs and Chemical Indicators (February 9, 2011) ("Steris Warning Letter")

The letters, taken together, make allegations under the following headings: Promotion of Unapproved Uses; Misleading Presentation; and Failure to Provide Adequate Directions for Use. The letters conclude that the cited advertising/promotional issues render the subject products misbranded.

***This alert merely summarizes the allegations contained in FDA's letters. It does not contain any analysis, opinions, characterizations, or conclusions by or of Covington & Burling LLP. As a result, the information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.***

#### Promotion of Unapproved Uses<sup>3</sup>

**Steris Warning Letter:** The website for Steris Corporation, as well as other promotional materials, made claims regarding the use of several chemical indicators and challenge packs that contain these indicators. When FDA cleared these devices, the Office of Device Evaluation (ODE) had asked the company to remove comparisons between biological indicators and chemical indicators from the indications for use, product labels, and 510(k) summary for the chemical indicators and challenge

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<sup>1</sup> Only enforcement letters posted to FDA's website in February 2011 are included herein. Letters issued in February but not posted to the website by February 28, 2011 will be summarized in our alerts for the months in which those letters are posted. FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) within the Center for Drug Evaluation and Research (CDER) did not post any applicable letters on its website in February.

<sup>2</sup> Dates referenced for the letters are issue dates.

<sup>3</sup> The letters issued by CDRH do not explicitly use this subheading, but the promotional allegations therein would fit within this category.

packs. ODE had also advised the company that chemical indicators should not replace the use of biological indicators. Therefore, according to FDA, the Steris chemical indicators cannot be said to “exceed” the performance of biological indicators. The package insert (PI) and a brochure for these devices, however, contained claims implying that the chemical indicators could replace the use of biological indicators, an indication for use that FDA claimed had not been cleared. For example, the PI claimed that the indicators “may be used to release all loads.” Similarly, a brochure stated that the devices were “next generation” and that they would reduce the wait, risk, and work involved in releasing loads. One of the promotional materials also stated: “Your goal is 100% successful sterilization. . . . The Verify SixCess indicator products are designed to measure Sterility Success.” According to FDA, however, the chemical indicators do not measure “Sterility Success.” Instead, they “measure only that a particular sterilizer cycle met the designated physical parameters for that cycle.” Finally, a flyer for the devices stated that one myth of Class 6 Technology was that “you cannot use Class 6 emulating indicators to release loads with implants.” The flyer rebutted this “myth” by stating that “FDA is very straightforward on this issue. Verify SixCess Chemical Indicators are cleared for the release of all loads & all items in the load, regardless of content.” FDA stated that it did not clear the Steris Verify Chemical Indicators for the release of loads with implants. In addition, FDA alleged that this statement was misleading because that is not FDA’s position, and these claims represented “a major modification to both the Intended Use and Indications for Use” of the indicators. FDA took the position, therefore, that the submission and clearance of a new 510(k) was needed before these claims could be made.

### Misleading Presentation

FDA’s letters contain the following allegations under a “Misleading Presentation” subheading:

**Novartis Untitled Letter:** A sales aid and print advertisement for the flu vaccine FLUVIRIN stated that the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices’s (ACIP) “new universal flu vaccination recommendation includes all persons 4 years of age and older.” However, the new ACIP recommendation actually states that “[r]outine influenza vaccination is recommended for all persons aged 6 months and older.” The sales aid and print advertisement therefore misrepresented the ACIP recommendation. Moreover, the sales aid and print advertisement “impl[ied] that FLUVIRIN meets the recommendation when, in fact, FLUVIRIN has not been demonstrated to be safe and effective for the entire population included in the recommendation (i.e., 6 months and older).” The PI for FLUVIRIN states that it is indicated for active immunization of persons 4 years of age and older.

### Failure to Provide Adequate Directions for Use

FDA’s letters contain the following allegations under a “Failure to Provide Adequate Directions for Use” subheading:

**Novartis Untitled Letter:** The sales aid for FLUVIRIN failed to provide adequate directions for use because it was disseminated without the PI.

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