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Client Alert

Unauthorized H1N1 Product Claims Targeted by Federal Agencies

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In the wake of the worldwide 2009 H1N1 pandemic, federal agencies are closely scrutinizing statements in advertisements and on labels that claim products are effective against the H1N1 flu virus. Makers of a host of products - from drugs and medical devices to dietary supplements and household consumer products - are trying to capitalize on the health concerns associated with this virulent new strain of influenza. Federal agencies are not only battling H1N1, they are also dedicating substantial resources to rooting out deceptive or unauthorized claims; and are taking aggressive enforcement action against companies that are marketing products with unapproved, uncleared, unauthorized or unsubstantiated H1N1 claims. Federal agencies most active include the U.S. Food and Drug Administration ("FDA"), the Federal Trade Commission ("FTC") and the U.S. Environmental Protection Agency ("EPA").

Of the three federal agencies, FDA is leading the H1N1 enforcement initiative. Pursuant to section 564 of the Federal Food Drug and Cosmetic Act, ("FDCA"), as amended by the Project Bioshield Act of 2004, FDA has the power to authorize the use of unapproved or uncleared medical products, or unapproved or uncleared uses of approved or cleared medical products, once a public health emergency has been declared. Only those FDA-regulated products that have received an "emergency use authorization" ("EUA") for H1N1 are allowed to make H1N1 claims. FDA has issued EUAs for only a handful of H1N1 medical products, including three antiviral drugs, disposable N95 respirators, and two diagnostic tests.

Since May 2009, FDA has issued 70 warning letters in connection with fraudulent marketing of products making H1N1 flu claims. The sheer number of these letters demonstrates FDA's active investigation and enforcement of fraudulent claims. Moreover, FDA's H1N1 warning letters contain a statement that the marketing of products with fraudulent H1N1 claims "is a potentially significant threat to the public health," and an admonition that failure to take corrective action could result in referral to FDA's Office of Criminal Prosecution for violations of the FDCA and other federal laws. This is much stronger language than is typically found in FDA warning letters.

On its website, the FDA maintains a running list of fraudulent H1N1 influenza virus products; as of November 10, 2009, this list contained 143 entries. FDA has also created a "widget" that can be added to any webpage and that allows consumers to search for and report fraudulent 2009 H1N1 flu products within the FDA's jurisdiction.

The FDA is coordinating its enforcement activities in this area with the FTC whose broad consumer protection jurisdiction extends to marketing claims for FDA-regulated products as well as products regulated by other agencies such as EPA. The FDA and FTC have taken unprecedented action in aggressively identifying, investigating and taking regulatory action against companies marketing unapproved and unsubstantiated H1N1 flu products. The agencies have issued two joint press releases in connection with their monitoring of H1N1 flu claims and are specifically targeting "promotions or internet site offering products for sale that claim to

diagnose, prevent, mitigate, treat or cure the 2009 H1N1 virus." In October 2009, the FDA and FTC issued their first ever joint warning letter to owners of a website making claims that products sold on the site will help prevent the spread of the H1N1 virus.

The FTC is similarly independently monitoring websites making H1N1 flu claims and is issuing warnings to site operators making unsubstantiated H1N1 flu claims. The FTC has also created a Consumer Alert, available on its website, cautioning the public to be skeptical about H1N1 flu claims.

The regulatory attention being paid to H1N1 flu claims also includes EPA, which has jurisdiction over sanitizers, disinfectants and other antimicrobial products (including wipes or sprays) intended for use on inanimate surfaces. Recently, at the Ninth Annual Antimicrobial Workshop, EPA officials stressed the importance of ensuring compliance with the requirements of the Federal Insecticide, Fungicide and Rodenticide Act - the federal law that governs these products. EPA expressly reminded industry participants that claims of efficacy against H1N1 viruses cannot be made without express EPA authorization. EPA is allowing some claims through establishment of a special, expedited procedure for approving the inclusion on labels of limited, specific statements that a product is effective against the 2009 H1N1 flu virus. In rolling out this new policy, EPA was careful to note that only the specific claims approved by the Agency, as set forth in the guidance, would be allowed. Any other claims or any unapproved claims would subject manufacturers, distributors and retailers to enforcement action by EPA.

Companies that want to label or market a product as effective against the H1N1 flu virus need to use extreme caution and ensure that they have the appropriate substantiation and regulatory authorization before any such claims are made on the product's label or in any marketing materials. For more information on these or other marketing claims, please feel free to contact the professional listed to the left, or your regular Crowell & Moring contact.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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