FDA Considers More Rigorous Enforcement For Homeopathic Products Over Safety Risks

New Labeling Is Possible; Pre-Market Testing Seems Unlikely

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After decades of delay, the Food and Drug Administration (FDA) is apparently getting around to considering again whether to subject homeopathic medicines to a higher regulatory standard. Most of those products are sold over the counter (OTC) and can be referred to as nutraceuticals, dietary supplements, and herbal products, although there is some disagreement as to whether herbs are part of the category. Some homeopathic products contain the same chemicals as a prescription pharmaceutical, but in much smaller amounts. Some contain plant or animal extracts. Traditionally, homeopathic products have been considered mostly harmless, although unproven in terms of efficacy.

But the FDA has become more concerned about their safety, which is not established by the agency as it is with conventional pharmaceuticals. Nor are homeopathic medicines even subject to the same standards as OTC medicines. In 1972, the FDA deferred homeopathic drugs from the safety reviews it planned for OTC drugs due to the unique nature of homeopathic medicine. The agency stated then that it would review them as a separate category later. Since 1988, the FDA has reviewed homeopathic drugs with regard to their ingredients, labeling, manufacturing, and some other yardsticks under the agency’s Compliance Policy Guide (CPG). Evidence of safety and proof of effectiveness are not required.

Derek J. Quinn, PharmD, RPh, Pharmacy Manager of Westlake Pharmacy in Portage, Michigan, wants the FDA to crack down on homeopathic products.

“Either homeopathic products must meet the same standards for safety and effectiveness as drugs or they must be labeled as dietary supplements with the statement that their claims have not been evaluated by FDA,” he says.

The Homeopathic Pharmacopeia of the United States includes more than 1,200 ingredients with official monographs; more than 500 new ingredient monographs have been added since 2004.

In April 2015, the agency held a two-day public workshop to elicit comments on potentially tougher enforcement policies. Weeks before that meeting, the agency issued a public warning to consumers not to rely on asthma products labeled as homeopathic. That warning lacked specifics, however. Chris Kelly, an FDA spokesman, says: “FDA has identified at least 23 OTC asthma-care drug products labeled as homeopathic, several of which are distributed through the mainstream retail stores. FDA has received several adverse events [reports] related to these products.”

As with conventional drugs and OTC drugs, there have been recalls of homeopathic products. In March 2014, Terra-Medica, Inc., voluntarily recalled 56 lots of Pleo Sanum products imported from Germany. The FDA determined, according to a press release, that the products had the potential to contain penicillin or derivatives of penicillin that may be produced during manufacturing. Those derivatives can result in a range of allergic reactions from mild rashes to severe and life-threatening anaphylactic reactions. There was no mention of adverse reactions having actually occurred.

Terry Cotter, president of Terra-Medica, spoke at the April FDA meeting. He says he was afraid the FDA was going to use the Pleo Sanum recall as the “false ‘poster boy’ for a larger strategy to obstruct access to safe and useful homeopathic and CAM [complementary and alternative medicine] medications and modalities generally.” He states that the German National Trade Supervisory Board’s good manufacturing practices authority has confirmed that these products are completely safe. “In all of this exchange we continued to remind regulators that there had never been a recorded incident of either a risk-associated adverse reaction or contamination in over 30 years of global sales,” he adds.

It is not clear whether anyone got sick from one of the Terra-Medica products. As with ingredients in other drug and biological products, homeopathic ingredients, even if highly diluted, can cause side effects, drug interactions, and allergic or other adverse reactions. The 2012 American Association of Poison Control Centers Annual Report indicated that there were 10,311 recorded poison exposure cases related to “homeopathic agents,” 8,788 of which were attributed to children 5 years of age and younger. Of the 10,311 reported cases, 697 required treatment in a health care facility.

The FDA isn’t the only regulatory agency to raise questions about homeopathic products. New York State Attorney General (AG) Eric T. Schneiderman sent cease-and-desist letters to four major retail chains earlier this year informing them they must stop selling certain herbal dietary supplements that were found to be problematic in DNA barcoding tests conducted for the AG’s office. Store-brand supplements from GNC, Target, Walgreens, and Walmart, including herbal supplements labeled as echinacea, garlic, ginkgo, ginseng, saw palmetto, St. John’s wort, and valerian, were tested. According to the AG, only 21% of the store-brand herbal supplements contained DNA from the plants listed on the products’ labels.

The American Botanical Council said the New York findings were based on only one testing technology from only one laboratory, making the results preliminary and requiring further substantiation.

Industry groups think that the 1988 CPG is fine and that no heightened measures are necessary.

continued on page 468
ures are needed. Will Woodlee, a legal counsel to the American Herbal Products Association, says the CPG provides a sufficiently substantial regulatory platform for homeopathic drug product oversight. The FDA will probably ratchet up its regulation of homeopathic products. But any more aggressive enforcement of labels and manufacturing is likely to be incremental given other, more important drug issues the agency is already struggling with.

REFERENCES