

Alert | Environmental



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EPA Expands RCRA Hazardous Waste Restrictions to a Broader Range of ‘Pharmaceuticals’ Including Dietary Supplements

If you are currently disposing of pharmaceuticals, including *dietary supplements*, into the dumpster or down the drain, you may want to reconsider that practice. New regulations promulgated by the Environmental Protection Agency (EPA) under the Resource Conservation and Recovery Act (RCRA) impact how health care facilities must dispose of unused pharmaceuticals. The new regulations treat some dietary supplements as pharmaceuticals and therefore regulate them as hazardous waste. Additionally, as of Aug. 21, 2019, health care facilities may be prohibited from disposing of pharmaceuticals and dietary supplements into the sewer, etc. This is in addition to RCRA already prohibiting disposal into the garbage or in some instances by recycling. Noncompliance comes with hefty fines.

Does your company qualify as a health care facility?

The new RCRA regulations only apply to health care facilities, the definition of which might seem limited to locations like physicians’ offices, hospitals, and pharmacies. However, regulators approved an expansive definition of health care facility in the new rules, including any location authorized to distribute, sell, or dispense pharmaceuticals (including regulated dietary supplements).

Do your products qualify as pharmaceuticals?

In the new regulations, “pharmaceutical” means any drug or dietary supplement for use by humans or other animals. The regulation incorporates the definition for dietary supplement created by the Federal Food, Drug and Cosmetic Act as amended by the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. 321(ff)). Under that definition, a product is a dietary supplement if it is intended to supplement a diet and contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clauses (A), (B), (C), (D), or (E).

Is your product a hazardous waste pharmaceutical?

Although most dietary supplements are considered pharmaceuticals under the above definition, only dietary supplements that meet the definition of “hazardous waste pharmaceutical” under RCRA are regulated. In this final rule, “hazardous waste pharmaceutical” means a pharmaceutical that (1) is a solid waste as defined in RCRA Section 261.2, and (2) exhibits certain characteristics such as toxicity (per part 261 subpart C) or is specifically listed by the EPA (per part 261 subpart D).

As to the first prong of the analysis, a pharmaceutical that is discarded (e.g., placed in the sewer, abandoned, trashed, or sometimes even recycled) may fit within the definition of solid waste in Section 261.2.

As to the second prong, assuming the dietary supplement isn’t specifically listed under subpart D, the pertinent question is whether the dietary supplement exhibits toxicity characteristics under subpart C. The EPA has promulgated a table in subpart C setting forth concentration thresholds for certain elements and chemicals such as cadmium, lead, mercury, arsenic, selenium, and chromium. When a product contains a listed element or chemical above the determined threshold, the product is considered to have a toxicity characteristic: cadmium’s threshold is 1.0 parts per million (ppm), lead’s threshold is 5.0 ppm, mercury’s threshold is .2 ppm, arsenic’s threshold is 5.0 ppm, selenium’s threshold is 1.0 ppm, and chromium’s threshold is 5.0 ppm. Accordingly, if you dispose of dietary supplements that may have concentrations exceeding any of these thresholds, those products may be classified as hazardous waste pharmaceutical and subject to the new regulations.

Penalties and implementation

Violations of RCRA Subtitle C allow for maximum civil penalty of \$74,552 per day, per violation. The sewer ban takes effect Aug. 21, 2019. If you are worried about your disposal practices given the new RCRA rules, it would be prudent to contact environmental legal counsel experienced in this area to ensure you do not run afoul of RCRA.

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