

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

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To Whom It May Concern:

This is to advise you that, subject to the terms set forth in this letter, the New York State Department of Environmental Conservation (“DEC” or “Department”) will exercise its authority to utilize enforcement discretion with respect to certain provisions of 6 NYCRR Parts 371. The DEC will exercise this authority regarding the provisions outlined below in lieu of full compliance with 6 NYCRR Parts 371 through 374 and 376 for certain nicotine-containing wastes. This enforcement discretion will become effective on August 21, 2019, or the date upon which this letter is issued, whichever date is later. All other provisions of the Part 370 Series remain in full force and effect and will be enforced.

In 1980, the United States Environmental Protection Agency (“EPA”) promulgated regulations that listed nicotine and salts (referred to commonly as “nicotine”) as acute hazardous waste P075. The assessment that this listing was based upon did not consider low-concentration nicotine-containing products, specifically smoking cessation or nicotine replacement therapy products, because those products had not yet been developed.

On February 22, 2019, EPA issued a final rule that amended the hazardous waste listing for nicotine and salts to address certain low-concentration nicotine containing products. The amendment published in 84 FR 5816-5950 (“Pharmaceuticals Rule”) amend the hazardous waste regulations to exclude Food and Drug Administration-approved over-the-counter nicotine replacement therapy (“FDA-approved OTC NRT”) products. This EPA regulation will not be effective in New York State unless and until adopted by the State.

These FDA-approved OTC NRT products have been reviewed and approved by the FDA as being safe and effective for people to use without a prescription. EPA has determined, based on the available information, that FDA-approved OTC NRTs do not meet EPA’s criteria for acute toxicity and should not be included in the hazardous waste listing for nicotine and salts. It should be noted that other nicotine containing products including, but not limited to e-cigarettes and nicotine-containing e-liquids, will not be excluded from the hazardous waste listing for nicotine and salts because these products are not regulated by the FDA and can contain levels of nicotine that are still considered to be acutely hazardous. This enforcement discretion allows the regulated community to use EPA’s amended hazardous waste listing for nicotine and salts (P075) in lieu of compliance with the hazardous waste regulations in 6 NYCRR Part 371 and removes an undue regulatory burden for generators of certain nicotine-containing wastes that do not meet the criteria for listing as a hazardous waste.

Procedure:

Nicotine-containing waste is not subject to regulation under 6 NYCRR Parts 371 through 374 and 376, provided that:

1. The waste meets the amended hazardous waste listing in 40 CFR 261.33(e) for P075:

Hazardous waste No.	Chemical abstracts No.	Substance
*	*	*
P075	154-11-5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	*
P075	154-11-5	Pyridine, 3-(1-methyl-2-pyrrolidiny)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).

2. The waste does not meet any other hazardous waste listing and is not a characteristic hazardous waste.

This enforcement discretion will be effective for eligible FDA-approved OTC NRTs managed within the borders of New York State, for as long as these materials remain within New York State. This policy in no way affects the hazardous waste management standards of other states which may regulate FDA-approved OTC NRTs under different standards.

Unless modified or rescinded sooner, this enforcement discretion shall automatically terminate on the effective date of DEC amendments to its Hazardous Waste Management regulations adopting EPA regulations in whole or in part as they pertain to the Pharmaceuticals Rule.

Sincerely,



Thomas S. Berkman
Deputy Commissioner, General Counsel.