

FAXBACK 12946
9441.1987(45)

CONTAINERS USED TO HOLD LISTED CHEMOTHERAPY DRUGS

JUN 16 1987

Mr. Fred Kamienny
Vice President
PRN Service, Inc.
1210 Morse
Royal Oak, Michigan 48067

Dear Mr Kamienny:

This responds to your letter of April 13, 1987, regarding the regulatory status of chemotherapy drugs and related supplies. In particular, you questioned whether the weight of the "empty" vial should be included in determining the amount of drug residues to be disposed.

As you pointed out, several chemotherapy drugs are listed in 40 CFR 261.33(f) (commonly known as the U-list). As such, these wastes are regulated under the EPA hazardous wastes regulations (unless subject to the small quantity generator exclusion). Included in the listing are the following discarded commercial chemical products, off-specification species, container residues, and spill residues:

- 1) chlorambucil (U035)
- 2) cyclophosphamide (U058)
- 3) daunomycin (U059)
- 4) melphalan (U150)
- 5) mitomycin C (U010)
- 6) streptozotocin (U206)
- 7) uracil mustard (U237)

Under EPA regulations governing the management of hazardous wastes, any container used to hold these chemicals (such as vials) are considered hazardous wastes unless these containers meet the criteria of an "empty container." Under the empty container provisions such vials are excluded from regulation if the material has been removed by pouring, pumping, and aspirating, and no more

than 1 inch of residue remains in the bottom of the vial or no more than 3 percent by weight of the total capacity of the container remains in the container. (See 40 CFR 261.7)

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The Agency is aware, however, that prudent practice dictates that materials contaminated with these chemicals (such as syringes, vials, gloves, gowns, aprons, etc.) not be handled after use. Therefore, to minimize exposure to these toxic chemicals, the

Agency recommends that the entire volume of waste be weighed and that there be no attempt to remove any residue from the vial before disposal.

Chemotherapy drugs that are not listed hazardous wastes are not regulated by EPA. However you should contact your State or local government regarding the management of these chemicals. Also, the National Institutes of Health (NIH) provides guidance on handling and management of antineoplastics. Contact Harvey Rogers, at NIH for further information. Mr. Rogers may be reached at (301) 496-7775.

If you should have any further questions regarding regulatory requirements for specific wastes, you may call RCRA Hotline at (800) 424-9346, or contact Mitch Kidwell, of my staff, at (202) 382-4805.

Sincerely,

Jacqueline W. Sales, Chief
Regulation Development Section