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PART 1310 —RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

§1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

- (a) The Administrator has reinstated the exemption for the drug products listed in paragraph (e) of this section from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. **822-823**, **830**, and **957-958**), to the extent described in paragraphs (b), (c), and (d) of this section.
- (b) No reinstated exemption granted pursuant to **1310.10** affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.
- (c) Changes in exempt drug product compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt drug product listed in paragraph (d) requires a new application for reinstatement of the exemption.
- (d) The following drug products, in the form and quantity listed in the application submitted (indicated as the "date") are designated as reinstated exempt drug products for the purposes set forth in this section:

Exempt Drug Products			
Supplier	Product name	Form	Date
[Reserved]			

[60 FR 32462, June 22, 1995]