

82 FR 9756

2/8/2017

②

As of: 3/22/17 10:55 AM
Received: March 17, 2017
Status: Pending_Post
Tracking No. 1k1-8vb5-nhuz
Comments Due: March 17, 2017
Submission Type: Web

PUBLIC SUBMISSION

Docket: NRC-2016-0227

Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses

Comment On: NRC-2016-0227-0002

Program-Specific Guidance About Exempt Distribution Licenses; Request for Comment on Draft NUREG

Document: NRC-2016-0227-DRAFT-0003

Comment on FR Doc # 2017-02574

Submitter Information

Name: Jena Rosenbaum

RECEIVED

MAR 22 10:05

REGISTRATION

General Comment

List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act:

The regulation is identifying an initial list of bulk drug substances that can used to compound drug products in accordance with certain compounding provisions of the Federal Food, Drug, and cosmetic Act. The Agency is proposing to place a six bulk drug substances on the list. I think this regulation is a good addition to 503A(c) (2) of the FD&C act. It sets criteria to look into the dangerous substances. It requires the physical and chemical characterization of the substance, any potential safety issues raised by the use of the substance, historical use of the substance, and any available information regarding the effectiveness or lack thereof of the drug compound.

SUNSI Review Complete
Template = ADM - 013
E-RIDS= ADM-03
Add= K. Wagner (KLW1)