

Food Recalls – Retail Consignee List Guidance

Office of Regulatory Affairs (ORA)
Office of Strategic Planning and Operational Policy (OSPOP)
Anthony C. Taube, Branch Chief, Human and Animal Food Policy Branch
April 10, 2019



Agenda

- FDA's Involvement in Food Recalls
- Public Information - 21 CFR Part 20
- Draft Guidance – Retail Consignee Lists & Release Criteria
- Why Limited?
- Impact to States with 20.88s



FDA & Food Recalls

- Voluntary – 21 CFR Part 7, Subpart C
- FDA Requested – 21 CFR Part 7, Subpart C
- Mandatory – Section 423 of the FD & C Act



Public Information

- 21 CFR Part 20 – Public Information – Subpart B - Fullest Possible Disclosure of Records
- Subpart D – Exemptions (e.g. Commercial Confidential Information or CCI)
- Subpart E, §20.91 – When necessary to effectuate an action
- What about information FDA doesn't have?

New Retail Consignee List Guidance



- Full Title: “Public Availability of Lists of Retail Consignees to Effectuate **Certain Human and Animal Food Recalls**”
- Draft Guidance published in the federal register in September, 2018.
- Describes FDA’s proposed policy for when and why it will release names of retail consignees during certain food recalls



New Retail Consignee List Guidance

- FSMA directed FDA to consider providing lists of consignees to the public as USDA does.
- Retail consignee information may be considered CCI because it can reveal supply-chain relationships.
- FDA may disclose CCI to the extent necessary to effectuate a recall (21 CFR §20.91).

New Retail Consignee List Guidance



- Proposed criteria for disclosing
 1. The food is not easily identified as being subject to a recall from its retail packaging (or lack thereof); and
 2. The food is likely to be available for consumption (i.e., given its shelf-life or perishability, it may still be in a consumer's possession).



New Retail Consignee List Guidance

- Issues
 - What does the consumer need to avoid use of the product (necessary to effectuate)?
 - Why not for all Class Is?
 - What about Class IIs?
 - Restaurants?

Impact to States with 20.88s

- States who may receive recall consignee lists now are prohibited from sharing/disclosing them.
- When FDA posts retail consignee lists under this policy, States will be able to point requestors to the FDA web site.

Questions/Discussion