Toddler drinks, formulas, and milks: Labeling practices and policy implications

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Abstract

Toddler drinks are a growing category of drinks marketed for young children 9–36 months old. Medical experts do not recommend them, and public health experts raise concerns about misleading labeling practices. In the U.S., the toddler drink category includes two types of products: transition formulas, marketed for infants and toddlers 9–24 months; and toddler milks, for children 12–36 months old.

The objective of this study was to evaluate toddler drink labeling practices in light of U.S. food labeling policy and international labeling recommendations. In January 2017, we conducted legal research on U.S. food label laws and regulations; collected and evaluated toddler drink packages, including nutrition labels and claims; and compared toddler drink labels with the same brand's infant formula labels. We found that the U.S. has a regulatory structure for food labels and distinct policies for infant formula, but no laws specifically for toddler drinks. Toddler drink labels utilized various terms and images to identify products and intended users; made multiple health and nutrition claims; and some stated there was scientific or expert support for the product. Compared to the same manufacturer's infant formula labels, most toddler drink labels utilized similar colors, branding, logos, and graphics.

Toddler drink labels may confuse consumers about their nutrition and health benefits and the appropriateness of these products for young children. To support healthy toddler diets and well-informed decision-making by caregivers, the FDA can provide guidance or propose regulations clarifying permissible toddler drink labels and manufacturers should end inappropriate labeling practices.

1. Introduction

What and how parents feed their infants and toddlers during the transition from exclusive breastfeeding or infant formula to the family diet is critical for establishing healthy dietary preferences and preventing obesity in children (Pérez-Escamilla et al., 2017). The American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) recommend exclusive breastfeeding for the first 6 months of life with the addition of complementary foods and the continuation of breastfeeding until at least 12 months of age (Gartner et al., 2005; American Academy of Family Physicians, n.d.). Iron-fortified infant formula is recommended for infants who are not breastfed. After 12 months, whole plain cow’s milk and healthy foods are advised (AAP Committee on Nutrition, 1988), (World Health Organization, 2013). Despite these recommendations, companies have introduced a category of toddler drinks, marketed for young children during this latter time period (Harris et al., 2016).

There are no consistently used terms for toddler drinks, defined here as products marketed as appropriate for children between 9 and 36 months old. We differentiate between two types of toddler drinks: “Transition formulas” are marketed for both infants and toddlers spanning 9 to 24 months, and are also known as “follow-up” or “follow-on” formulas. “Toddler milks,” also known as “growing up” milks, are marketed for young children between 12 and 36 months.

Although toddler drinks are marketed as advantageous for toddlers’ nutrition and growth (Harris et al., 2016), experts do not recommend them. The World Health Organization (WHO) deems toddler drinks “unnecessary” and “unsuitable” as a breastmilk substitute (World Health Organization, 2013). Further, AAFP notes that toddler drinks hold no “advantage” over whole milk and a nutritionally adequate diet (AAP Committee on Nutrition, 1988). Most toddler drinks are primarily composed of powdered milk, corn syrup solids or other added caloric sweeteners, and vegetable oil, and contain more sodium and less protein than whole cow’s milk (Harris et al., 2016). The American Heart Association recommends against serving added sugars (including the sweeteners in these products) to children less than two years of age (Vos...
et al., 2017), and experts express concern that these products may increase young children’s preferences for sweet tastes, negatively impacting weight outcomes (Pérez-Escamilla et al., 2017). Furthermore, U.S. toddlers’ diets have been found to meet or exceed recommendations for most nutrients (Ahluawalia et al., 2016), while the AAP recommends that parents concerned about picky eating and potential missing nutrients should use a multivitamin instead of toddler drinks (O’Connor, 2009).

Previous research has consistently highlighted concerns that common marketing and labeling practices for infant formula may mislead parents to believe that these products provide benefits over breastfeeding (McFadden et al., 2016; Hughes et al., 2017). However, few studies have examined toddler drink marketing, including product labeling. WHO expressed concern that toddler drink packaging, branding, and labeling practices that closely resemble those of infant formula, may confuse consumers (World Health Organization, 2013). Three studies found that companies marketed infant formula and toddler drinks as part of the same line of products using existing brand names, and similar labels, colors, and logos (Baker et al., 2016), (Berry et al., 2012), (Pereira et al., 2016). Further, they found that the packaging displayed brand names in larger text than the text that identified the actual product category. Another study found that expectant mothers have difficulty differentiating between infant formula and toddler drinks when viewing advertisements (Berry et al., 2010). Furthermore, U.S. companies have substantially increased their advertising spending for toddler drinks in recent years, using messaging that implies that these products are beneficial or even necessary for toddlers’ growth and mental performance and offer a solution for picky eating (Harris et al., 2016).

In 2016, the World Health Assembly and WHO recommended that toddler drinks should be included in prohibitions against promoting breastmilk substitutes (WHO, 2016a; World Health Assembly, 2016). In addition, they stated that messaging about products for this age group should support optimal diets, include a statement on the importance of breastfeeding, not promote bottle feeding, and not use images of bottles to imply that a product is intended for infants under 6 months (WHO, 2016a; World Health Assembly, 2016). They called on member states to incorporate guidance into national laws, while taking into account existing legislation and policies, to define products appropriate for infants and young children with a focus on limiting added sugars and salt (WHO, 2016a; WHO, 2016b).

Although the U.S. has not adopted policies to comply with the WHO’s International Code of Marketing Breastmilk Substitutes (WHO, 1981), it has a substantial regulatory framework for food labeling that applies to this category. Congress enacts food labeling legislation and the U.S. Food and Drug Administration (FDA) is the federal agency responsible for regulating packaged food labels. (States are preempted, or prohibited, from regulating food labels in the manner described in this paper.) The FDA has the authority to enact regulations fixing and establishing a definition, standard of identity, and reasonable standard of quality for any food (21 USC §341, n.d.). The agency also has the authority to issue guidance documents, which are not binding on companies, to provide industry members guidance on proper labeling practices.

This study fills a gap in the research by documenting current toddler drink labeling practices and examining how U.S. policies and the federal regulatory framework can be utilized or expanded to support clear, transparent, and truthful labeling of toddler drinks. The objective was to assess strategies for the FDA to address toddler drink labeling practices to enable caregivers to make well-informed decisions related to feeding very young children.

2. Methods

In order to examine toddler drink labels in light of the U.S. food labeling framework, this study first examines U.S. food labeling policies. Then it identifies toddler drink products in the market and critically evaluates toddler drink labels, including comparing them to infant formula labels. All research was completed as of January 14, 2017.

2.1. Labeling policies

One legal researcher conducted research to determine the federal regulatory framework related to toddler drink labels as of January 14, 2017. Using LexisNexis, the sections of the United States Code and Code of Federal Regulations (collectively “laws”) related to food labels were analyzed for their applicability to toddler drinks. This included reviewing all infant formula labeling laws and general food labeling requirements (including prohibitions against misbranding). Additionally, key word searches using the terms “toddler” and “infant” were conducted within the labeling laws on LexisNexis and on the FDA’s website.

As used in this paper, the federal Food, Drug, and Cosmetic Act defines the term “label” to mean a display of written, printed, or graphic matter upon the immediate container or retail package of any food (21 USC §321, n.d.). FDA regulations define the principal display panel of a food package as the part of a label most likely to be displayed, presented, shown, or examined by consumers when displayed for retail sale (21 CFR §101.1, n.d.). The product's statement of identity, or name of the food, must appear on the principal display panel (21 CFR §101.3, n.d.). Additionally, FDA regulations require an ingredient list and Nutrition Facts panel (21 CFR §101.2, n.d.).

2.2. Toddler drink products and labeling: collection and coding

To identify drinks marketed as appropriate for toddlers, researchers utilized a list from a previous study of food and beverage products marketed for children up to age 3 years (Harris et al., 2016) and conducted internet searches for additional relevant products available in the U.S. as of January 14, 2017.

Researchers visited local retailers and took photos of the entire package for each toddler drink product identified. One product, Gerber Good Start 3 Soy, was not available locally, so researchers used the package images available on Walmart.com. Data collection was completed by January 14, 2017.

Researchers coded the principal display panel of each toddler drink product to gather information on the statement of identity, brand name, font size, and age of the child for which the product was intended. Then, researchers coded all claims and images on product packages. Claims were defined for this study as statements, symbols, vignettes, or other forms of communication anywhere on the package that characterized the product, suggested how to prepare or use it, or provided expert, health, nutrition, or ingredient information (21 CFR §101.13-§101.14, n.d.). Data extracted included each type of message or image, the age of the child the product was intended to serve, and whether the package disclosed an infant formula nutrition panel or standard Nutrition Facts panel required for all other types of beverages.

To compare packaging of toddler drinks and infant formula, the principal display panel for each toddler drink was compared to the principal display panel of the same manufacturer’s powder infant formula, if one existed, as found for purchase online as of January 14, 2017. Using the same methods as a previous study (Pereira et al., 2016), researchers coded similarities and differences between the two products’ brand names, brand logos (images identifying the brand that are not the brand name such as mascots and symbols), additional images (e.g., cartoon character excluding the brand logo), and background colors and graphics (scheme, design, layout).
3. Results

3.1. Labeling regulations

The legal research uncovered extensive regulations related to infant formula (21 CFR Parts 106, 107, n.d.) but no specific regulations related to toddler drinks. For example, FDA regulations define an infant as a person not > 12 months old and a child as a person between 12 months and 12 years old (21 CFR §105.3, n.d.); there is no similar definition for toddlers. Related to labeling, FDA regulations for infant formula include standard of identity requirements, an infant formula nutrition panel, requirements for permissible and impermissible claims, directions for use, and a required statement to use as directed by physicians (21 CFR §107.10, n.d.), (21 CFR §107.20, n.d.). Moreover, in 2016, the FDA issued draft guidance for industry on structure/function claims for infant formula labels (FDA, 2016). Conversely, for toddler drinks, there are no name or claim requirements, required directions for use or required disclaimers, nor a requirement that toddler drink packaging must be distinguished from infant formula packaging.

Nonetheless, requirements for all packaged food do apply to toddler drinks. All foods are required to have a statement of identity presented in bold type on the principal display panel and in a size reasonably related to the most prominent printed matter, including the brand name (21 CFR §101.3, n.d.). Because there is no federally required standard of identity for toddler drinks, manufacturers are required to use a common or usual name if there is one, or an “appropriately descriptive term” for the product (21 CFR §101.3, n.d.). All foods are also subject to misbranding prohibitions. A food is misbranded if, among other labeling deficiencies, it is false or misleading, offered for sale under the name of another food, or it does not display required information prominently (21 USC §343, n.d.).

3.2. Toddler drink products and labeling

Table 1 reports the U.S. toddler drink products identified by researchers, totaling 17 products from eight manufacturers. Five products were marketed as intended for children 9 months through 18 or 24 months (i.e., transition formulas) and 12 products were marketed for toddlers over 1 year or between 12 and 24 or 12–36 months (i.e., toddler milks). All of the transition formulas utilized an infant formula label and all of the toddler milks utilized a Nutrition Facts panel.

There was no consistent statement of identity for these products; rather, the labels used various product names, typically combining infant and/or toddler with drink, milk, or formula. One transition product, Target’s Toddler Beginnings, called itself infant formula while the rest of the transition formulas called themselves “infant and toddler formula.” The majority of toddler milks called themselves “toddler formula,” “toddler drink,” “toddler milk,” or “milk drink.” Of all products examined, Similac’s and Earth’s Best’s toddler milk products most prominently displayed the statement of identity, “toddler drink” and “toddler formula,” respectively. The principal display panels for the Nido products were the only ones that did not include the word “toddler” and their statements of identity (milk beverage and dry whole milk) were unique among the other products. The Nido products were also the only to describe the contents in both Spanish and English. See Appendix Table 1 for images of all toddler drinks.

As reported in Table 2, all toddler drink packages included one or more nutrient/ingredient claims linked with child health/development claims (e.g., structure/function claims), and all but one also included multiple nutrient/ingredient claims alone. See Appendix Table 2 for definitions and examples of terms used in Table 2. Most packages explicitly stated that the product was designed for toddlers and many claimed that there was a scientific basis for serving the product, or that experts recommend the product or an ingredient in the product. For example, two Enfagrow products stated that it was the “#1 brand recommended by pediatricians for products” with a footnote, “Among products labeled for toddlers under 2.”

Three transition formulas and eight toddler milks showed or mentioned a cup, while all transition formulas and two of the toddler milks showed or mentioned a bottle. Labels on two transition formulas and one toddler milk directed users to contact their physicians before use. For example, Baby’s Only Toddler Formula showed a series of three

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Table 1

<table>
<thead>
<tr>
<th>Product</th>
<th>Stated age on label</th>
<th>Nutrition label type</th>
<th>Most prominent on label</th>
<th>Second most prominent</th>
<th>Statement of identity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transition formulas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enfagrow Toddler Transitions</td>
<td>9–18 months</td>
<td>Infant formula</td>
<td>Enfagrow</td>
<td>Toddler transitions</td>
<td>Infant and toddler</td>
</tr>
<tr>
<td>Enfagrow Toddler Transitions Gentlease</td>
<td>9–18 months</td>
<td>Infant formula</td>
<td>Enfagrow</td>
<td>Toddler transitions</td>
<td>Infant and toddler</td>
</tr>
<tr>
<td>Enfagrow Toddler Transitions Soy</td>
<td>9–18 months</td>
<td>Infant formula</td>
<td>Enfagrow</td>
<td>Toddler transitions</td>
<td>Infant and toddler</td>
</tr>
<tr>
<td>Gerber Good Start 3 Soy</td>
<td>9–24 months</td>
<td>Infant formula</td>
<td>Gerber</td>
<td>Soy</td>
<td>Infant and toddler</td>
</tr>
<tr>
<td>Target Toddler Beginnings</td>
<td>9–18 months</td>
<td>Infant formula</td>
<td>Toddler Beginnings</td>
<td>Infant formula with iron</td>
<td>Infant formula</td>
</tr>
</tbody>
</table>

Toddler milks

<table>
<thead>
<tr>
<th>Product</th>
<th>Stated age on label</th>
<th>Nutrition label type</th>
<th>Most prominent on label</th>
<th>Second most prominent</th>
<th>Statement of identity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earth’s Best Organic Toddler Formula (vanilla)</td>
<td>1 year +</td>
<td>Nutrition facts</td>
<td>Earth’s Best</td>
<td>Toddler formula</td>
<td>Toddler formula</td>
</tr>
<tr>
<td>Enfagrow Toddler Next Step 1–3 years old</td>
<td>12–24 months</td>
<td>Nutrition facts</td>
<td>Enfagrow</td>
<td>Toddler next step</td>
<td>Toddler formula</td>
</tr>
<tr>
<td>Gerber Good Start 3 Grow</td>
<td>12–24 months</td>
<td>Nutrition facts</td>
<td>Gerber</td>
<td>Grow</td>
<td>Toddler drink</td>
</tr>
<tr>
<td>Happy Tot Grow &amp; Shine</td>
<td>12–24 months</td>
<td>Nutrition facts</td>
<td>Grow &amp; Shine Organic</td>
<td>Toddler</td>
<td>Toddler milk</td>
</tr>
<tr>
<td>Nature One Baby’s Only Organic Non-GMO Diary Toddler Formula</td>
<td>1 year +</td>
<td>Nutrition facts</td>
<td>Baby’s Only</td>
<td>Organic</td>
<td>Toddler formula</td>
</tr>
<tr>
<td>Nestle Nido 1+</td>
<td>1 year +</td>
<td>Nutrition facts</td>
<td>NIDO</td>
<td>1+</td>
<td>Milk beverage</td>
</tr>
<tr>
<td>Nestle Nido Fortificada</td>
<td>1 year +</td>
<td>Nutrition facts</td>
<td>NIDO</td>
<td>Nestle</td>
<td>Dry whole milk</td>
</tr>
<tr>
<td>Similac Go &amp; Grow</td>
<td>12–24 months</td>
<td>Nutrition facts</td>
<td>Go and Grow</td>
<td>Toddler drink</td>
<td>Toddler drink</td>
</tr>
<tr>
<td>Similac Go &amp; Grow NON-GMO</td>
<td>12–24 months</td>
<td>Nutrition facts</td>
<td>Go and Grow</td>
<td>Toddler drink</td>
<td>Toddler drink</td>
</tr>
<tr>
<td>Similac Go &amp; Grow Sensitive</td>
<td>12–24 months</td>
<td>Nutrition facts</td>
<td>Go and Grow</td>
<td>Toddler drink</td>
<td>Toddler drink</td>
</tr>
<tr>
<td>Similac Go &amp; Grow Vanilla</td>
<td>12–24 months</td>
<td>Nutrition facts</td>
<td>Go and Grow</td>
<td>Toddler drink</td>
<td>Toddler drink</td>
</tr>
<tr>
<td>Target Toddler Next Stage</td>
<td>1 year +</td>
<td>Nutrition facts</td>
<td>Toddler Next Stage</td>
<td>Milk drink</td>
<td>Milk drink</td>
</tr>
</tbody>
</table>

* Prominence was determined by the largest/boldest font size and when similar, which was first from top to bottom or left to right.
* Not including additional words denoting health, nutrition, or the addition of vitamins and minerals.
pictures depicting a bottle and stated: "Baby's Only Organic is intended for a toddler 1-year of age and older or as directed by a healthcare professional," which is a variation on directing users to a physician.

Table 3 reports the comparison between the principal display panel for toddler drinks and the same manufacturer's infant formula (for manufacturers with both types of products). See Appendix Table 3 for images of the toddler drinks compared to infant formula principal display panels coded. Most of the transition formulas had almost identical labels to the corresponding infant formulas, with the exception of Target's products which prominently stated the intended user (toddler or infant) and used different background colors. In comparing the toddler milk products with the infant formula products by the same manufacturers, most had similar to almost identical labels. Gerber Good Start and Mead Johnson's toddler drink products were the most similar to their infant formula packaging. The most dissimilar were Earth's Best products because of the vastly different background colors utilized, and Similac's products. Similac's toddler milk had a graphic stick-figure of a child that formed the word Toddler Drink, which was not present on its infant formula; yet, both products still used the same background colors and graphics.

4. Discussion

This evaluation of toddler drinks identified 5 transition formulas and 12 toddler milks, with wide variation in packaging claims, images, and names to identify the products. There are no FDA regulations or guidance documents specifically devoted to toddler drinks' standard of identity, ingredients, nutrition labeling, or claim requirements. As a result, toddler drink labels do not consistently provide the same information or clearly identify the product. Moreover, some labels did not seem to follow FDA's general regulations for all food labels, as described directly below. Additionally, as found in other studies (Baker et al., 2016; Berry et al., 2012; Pereira et al., 2016; Berry et al., 2010), many toddler drink product labels were visually similar to the same manufacturer's infant formula label. Given these issues with toddler drink labeling and the fact that these products are not recommended by
peditcians or public health experts, toddler drink labels may mislead caretakers of young children about the healthfulness or necessity of these products. This study builds on previous research to demonstrate that manufacturers’ marketing practices may undermine the diets of very young children.

Toddlers drink labels did not seem to follow all FDA regulations. With the exception of Similac’s and Earth’s Best’s toddler milks, the products’ labels did not prominently disclose the statement of identity in bold type reasonably related to other words, as required by the FDA. Furthermore, the majority of transition products called themselves “infant and toddler formula,” but this is not a clear or legally defined term. Target’s transition product identified itself as infant formula, but since it is indicated for children 9–18 months, the name does not align with the FDA’s definition of an infant as not > 12 months old. Moreover, toddler drinks often used the term “formula,” which previous research has suggested could give the perception that toddler drinks are appropriate substitutes for infant formula or breastmilk (Pereira et al., 2016). Interestingly, only the Nido products did not use the word “toddler” on the principal display panel, but it is unclear if this is due to the lack of an equivalent word in Spanish or another reason.

The variety of names used to identify these products (e.g., toddler milk, toddler formula), with no clear definitions for terms used, may be confusing to consumers.

All product labels made claims related to nutrition, health, and/or expert recommendations that may lead consumers to believe these products are necessary and healthy, when in fact they are not recommended by health experts and there is no evidence that they are nutritionally superior to healthy food and whole milk. Moreover, some labels had claims with an unclear scientific basis (Hughes et al., 2017). For example, Mead Johnson provided no documentation to support or explain its claim that Enfamil Grow is the “#1 brand recommended by pediatricians.” As noted, the AAP and the AAFP, which represent pediatricians and family physicians, do not expressly recommend toddler drinks (American Academy of Family Physicians, n.d.; AAP Committee on Nutrition, 1988).

Most toddler drink product labels were also visually similar to the same manufacturer’s infant formula label and promoted the same brand, increasing the likelihood of confusion. When compared to the same manufacturers’ infant formula, packaging for Gerber Good Start and Mead Johnson’s toddler drinks were almost identical. Both of these brands highlight an additional concern with similarities between product labels: brands offer products for multiple stages spanning different age ranges, so it is not necessarily clear when caregivers should switch to another product or stop using them and switch to cow’s milk as recommended by the AAP, AAPF, and WHO. In addition, seven products depicted images of bottles, which the WHO advised against as confusing the products with infant formula (WHO, 2016a). In sum, there is a strong likelihood of confusion about appropriateness of serving toddler drinks and differences between infant formulas and toddler drinks.

The FDA has the authority to issue regulations fixing and establishing a definition, standard of identity, and reasonable standard of quality for any food, including toddler drinks (21 USC §341, n.d.). The FDA could require or provide guidance to companies to ensure appropriate labeling of toddler drinks, including: clearly differentiating among infant formula, transition formula, and toddler milks to avoid consumer confusion and minimize misbranding; utilizing appropriate health and nutrition claims; and avoiding false and misleading statements. The FDA might also consider extending current labeling protections for infant formula to toddler drinks, by requiring that toddler drink labels also advise consumers to “consult a physician” about product use, and by extending its draft guidance on structure/function claims to toddler drinks. To protect infants, the FDA might additionally consider requiring a disclaimer on toddler drinks that notifies users that the product is not intended for children < 12 months or as a substitute for breastmilk or infant formula. Prior to any FDA regulatory action, manufacturers should voluntarily amend their labeling practices in accordance with WHO recommendations and existing FDA regulations to support informed consumer decision-making and avoid potential misbranding concerns.

This study adds to the literature by examining U.S. policy related to toddler drink product labels and evaluating how U.S. law and international recommendations relate to toddler drinks available for retail sale in the U.S. We found the labels do not consistently align with FDA requirements or WHO recommendations and may be confusing to parents and other caregivers.

Nonetheless this study has limitations. We did not analyze the claims made on manufacturers’ or online sellers’ websites. In addition, we did not collect sales or purchase data to determine how many caregivers are purchasing these products; survey consumers to ascertain their knowledge of toddler drinks; or examine how caregivers interpret the claims and other information on toddler drink labels. These are areas ripe for future research. It is also noteworthy that this market is rapidly evolving, so researchers should closely monitor changes in product offerings and labeling claims. After data collection ended in this study, we found several new toddler drink products by brands included in this study. For example, Happy Tot created a product line that includes an infant formula stage 1 (0–12 months), infant formula stage 2 (6–12 months), and toddler milk (1 year and up), all with almost identical packaging, branding, logos, and graphics (Happy Tot Family Brands, n.d.). See Appendix Fig. 1.

5. Conclusion

Toddlers drinks are unnecessary, and may undermine a nutritious diet, yet manufacturers have significantly expanded their marketing of these products in recent years. It is thus important for labels to be clear, transparent, and accurate. Manufacturers should agree on and consistently use one statement of identity for similar products and discontinue practices that do not align with FDA regulations and expert recommendations (e.g., the use of packaging similar to infant formula, questionable claims, and depictions of bottles). Alternatively, and especially if manufacturers do not act voluntarily, the FDA should enact regulations to ensure that toddler drinks are clearly and accurately labeled. The FDA and food manufacturers should work together to end the inappropriate labeling of toddler drinks and ensure caregivers have appropriate information to nutritionally feed their children.

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Potential conflicts of interest

The authors have no conflicts of interest relevant to this article to disclose.

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21 CFR §101.1 n.d.
21 CFR §101.2 n.d.
21 CFR §101.3 n.d.
21 CFR §105.3 n.d.
21 CFR §107.10 n.d.
21 CFR §107.20 n.d.


