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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: **Docket No. 02N-0204**; comments concerning the March 14, 2003 Proposed Rule, "Bar Code Label Requirement for Human Drug Products and Blood"

Dear Sir/Madam:

Novartis Consumer Health, Inc. (NCH) is the over-the-counter (OTC) subsidiary of Novartis Corporation. The comments submitted are on behalf of NCH and are separate and apart from any comments submitted on behalf of Novartis Pharmaceuticals Corporation.

The comments provided are specific to OTC drugs. NCH is not submitting comments regarding the application of the proposed rule for bar codes to prescription drugs, medical devices or biologics.

NCH strongly supports efforts to reduce medication errors, which may ultimately reduce adverse drug events in the healthcare setting. In this regard, we urge FDA to consider all elements of phasing in this requirement over a designated time period from a manufacturer, consumer and professional health community perspective.

Comments:

1. Under 201.25(b), we request FDA to exclude OTC samples from the rule in the same manner by which prescription samples were excluded.
2. *FDA invited comments on the terms used to describe OTC drugs that should be subject to the bar code requirements.* FDA proposed OTC drugs "commonly used in hospitals" and "dispensed pursuant to an order" should be subject to bar code requirements. Though these terms may provide clear, concise direction to the hospital/institution community, they do not necessarily provide clear direction to the OTC industry who are responsible for OTC product labeling. NCH suggests the applicability of bar codes might be better clarified by regulation via exclusion rather than inclusion. To avoid confusion and inconsistent application throughout the OTC industry, FDA should list those products/categories of products and/or ingredients that do not require bar codes. Such a list would provide clear direction rather than leave discretion as to the intent of a medically based definition.

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3. In the proposed rule, FDA states, "The proposal would apply to any manufacturer, repacker, relabeler, or private label distributor who sells a specific package of an OTC drug product to hospitals. It would not apply to all packages of a specific OTC drug product.....We would interpret, 'commonly used in hospitals' to include OTC drugs that are sold to hospitals, packaged for institutional use, labeled for institutional use, or marketed, promoted, or sold to hospitals through drug purchasing contracts or catalogues."

    a. Throughout the proposed rule FDA refers to hospitals. However, in the above paragraph "institutional use" is called out. It is necessary to have a clear definition of the sites to which bar coded product must be distributed. An "Institution" may be defined in many ways. Dictionary definitions indicate that the term may include things such as prisons, out-patient clinics, grammar schools, universities, business health service sites, or any organized setting. It appears that the intent is to require bar codes on OTC products "dispensed pursuant to an order". However, "institutions" exist where "an order" is not provided by a doctor before an OTC drug is dispensed. Clearly, either the rule should be specific to "hospitals" or the term "institution" must be defined in the narrowest of terms.

    b. Clarification is needed for the intent of, "It would not apply to all packages of a specific OTC drug product" as it applies to hospital sales. In NCH's current sales structure, hospitals, purchasing groups, etc. buy products from a slightly modified open stock catalogue of products. This catalogue includes all retail and a few hospital specific SKUs. From the wording above, NCH is unclear if **only** bar coded SKUs can be made available to hospitals or if at least one SKU of a product must have a bar code. NCH believes if one SKU of a product is made available with a bar code in compliance with the final regulation, then the other non-bar coded SKUs of that same product should be allowed to remain in the company's catalog or price list used to generate sales from hospitals.

    Recognizing bar coded products will be more expensive to manufacture and thus will have a higher per unit cost to hospitals, NCH does not believe the overall health care system would benefit by forcing hospitals to pay more for bar coded products prior to having systems in place to utilize those bar codes. In the proposed rule, FDA speculates about hospitals "achieving the installation of complete systems within 10 years". For hospitals that do not invest in bar code technology until the end of the proposed 10 years, the option to continue purchasing OTC products at the lowest per dose price (usually the largest package size and in this case without bar codes) should be maintained. Such an allowance would help hospitals keep drug costs to a minimum while they invest in bar code technologies.

4. NCH is evaluating strategies for bar-coding products for sale in hospitals. Our focus has been on three (3) basic approaches. A brief explanation along with some issues and questions follows:

   (a) Addition of bar codes to existing SKUs to meet the requirements – The distinct disadvantage of this approach is that the product UPC codes must include product NDC numbers. The complexities and expenses involved in changing a product UPC code has been previously addressed by the OTC industry and will not be further discussed. Due to the challenges this would raise for our retail customers, and the expected resultant economic consequences for NCH, this option was deemed an unacceptable approach for NCH.

   (b) Creation of new SKUs which meet requirements for sale in both the retail and hospital environment – This option overcomes the UPC issue since new SKUs are assigned new UPC codes which could be constructed to include product NDC numbers. Although this option overcomes the UPC issue, it requires both human readable and bar code information on packages which are already limited in label space. The expense and size of packaging needed to bear consumer friendly information along with a bar code on the various levels of packaging is under evaluation. Additionally, the impact of requirements for child resistant closures must be considered.

   The proposed rule notes that the FDA intends to redefine the NDC number. The impact of this redefinition is currently unclear and it complicates industry's ability to fully evaluate options for compliance.

   (c) Creation of a "hospital use only" line of products. This option would comply with the bar code regulation by establishing a "hospital use only" line of products. The option appears promising but leads to some questions:

      (1) Currently, this option requires both extensive human readable and bar code information on packages. Since the bar code would be used to identify the product, these products could be sold with a minimum of human readable information on the smallest units. NCH suggests that the final rule establishes the minimum human readable information required to appear on the smallest unit of bar coded packaging when the SKU is labeled, "for hospital use only".

      (2) NCH requests clarification on the applicability of the requirements of 16CFR Part 1700 to OTC bar coded products labeled "For hospital use only". Child-resistant packaging should not be required as the affected products would not be intended for use as "household substances". [1] Though the "substances" in question might normally fall within the scope of the definition, the specific packages in question should not. Finally, NCH does not believe a product labeled, "For hospital use only", should be required to bare the statement, "This Package for Households Without Young Children" as required by 16CFR1700.5(a)(1).

[1] 16CFR1701.3 defines "household substance" as "any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individual in or about the household".

5. Proposed 201.25(c)(1) would require the bar code for drugs and biological products (other than blood and blood products) to be any linear bar code in the UCC/EAN standard. The rationale behind limiting industry to the use of linear codes appears to be the cost of scanners and related equipment in the hospital sector. FDA states, "Some scanner manufacturers may be able to upgrade or modify an existing scanner to read newer symobologies, while other scanners, due to their age or the manner in which they were made, might not be capable of being upgraded. We invite further comment on this point." NCH agrees with the proposal to utilize EAN.UCC standards, however believes the symbologies should not be limited to linear. As UCC/EAN standards are developed for various symbologies (i.e., data matrix), the final rule should be worded to allow for the use of them. The objective of the proposed rule is written as, "to enable the health care sector to utilize technological solutions to reduce preventable adverse drug events (ADEs) associated with medication errors in hospitals."

   As per Webster's Ninth New Collegiate Dictionary :
   "Technological" – (1) of, relating to, or characterized by technology (2) resulting from improvements in technical processes that increases productivity of machines and eliminates manual operations or operations done by older machines
   "Solution" – 1(a) an action or process of solving a problem (b) an answer to a problem

   Looking at the above definitions, limiting the industry to linear bar codes so hospitals do not have to invest in either new or updated equipment is contrary to the stated objective of the proposed rule. NCH requests that FDA consider allowing industry to use any symbology for which the EAN.UCC has issued appropriate standards.

   In considering the financial implications of the rule, it is NCH's understanding that when patient (consumer) safety is at risk, the FDA's mandate toward consumer safety precludes most financial considerations. Whether the mandate has been child-resistant packaging for an application where no child-resistant packaging was available (i.e., CR requirement for lidocaine and dibucaine when no CR tubes were commercially available); providing up to date scientific support for older monographed ingredients, or investing in new packaging/labeling solutions to meet the Drug Facts space requirements; the OTC drug industry consistently rises to the financial challenges posed by government regulations.

   For the OTC drug industry, this is done in a competitive retail environment where the answer is not as simple as raising prices. Further, this regulation governs what the industry can do, the hospitals are not governed by this regulation and therefore it seems irrational to tailor these requirements based upon what hospitals may or may not do to ensure the safety of their patients.

   FDA states, "we recognize that the bar codes ability to prevent medication errors depends on many external factors outside this rule, such as the availability of bar code scanners, computer software that can process the bar code information and compare it against patient information, training health care professionals to use scanning equipment, and the willingness of hospitals to invest in bar code scanning equipment." It is evident that scanner cost is only one of the factors that will play into the financial equation for hospitals, and therefore it should not be used as a basis for limiting technological solutions available to industry.

6. The FDA invited comment(s) on whether the implementation period can and should be shortened. NCH does not believe shortening the implementation period will be of significant benefit as the vast majority of hospitals are not presently ready to use bar codes to reduce medication errors. The three year time period replicates what was allowed for Drug Facts. Also, as previously mentioned, FDA has stated its intent to "revise the drug establishment registration and listing regulations to redefine the NDC number..." This redefinition may affect every drug SKU marketed by NCH and will draw on the same resources needed for bar code implementation. NCH does not see merit in moving forward to execute the bar code initiative until the new NDC regulations are published and analyzed for impact by the OTC drug industry. It is difficult to comment on how these two regulations would best be implemented, together or separately, without an understanding of the requirements of the new NDC regulations. It may be best to have an implementation period for the bar code regulation distinct from and subsequent to that of the new rule on NDC number assignment and drug listing.

In summary, NCH believes that the proposed rule should be revised to:

- provide exemptions for OTC samples and specific product categories
- include precise definitions for "hospital" and "institution"
- provide exemption from child-resistant package requirements for SKUs marked for "hospital use only"
- limit the amount of required human readable text on SKUs that include bar codes and are labeled for "hospital use only"
- allow product catalogues/price lists intended to solicit hospitals sales to include both bar coded and uncoded SKUs as described above
- allow the use of any symbology for which the EAN.UCC has issued appropriate standards
- provide for an implementation period that considers the compliance date for the proposed rule to redefine the NDC number/drug listing requirements

NCH supports the bar code initiative and looks forward to working on innovative solutions that will help the hospital community utilize our products safely and effectively.

Respectfully submitted,

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