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June 5, 2000

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

Copy to: FDADockets@oc.fda.gov

Regarding: Notice of participation, public meeting on June 28 and 29, 2000 to discuss the Agency's approach to regulating over-the-counter drug products

BD (Becton, Dickinson and Company) produces OTC drugs for professional use. BD produces both monograph drugs, such as povidone iodine swabs for skin preparation prior to incision or catheterization, and NDA OTCs, such as chlorhexidine antimicrobial scrubs for health care personnel. BD also sells "traditional" OTC products, such as first aid alcohol antimicrobial wipes for use by consumers. We welcome this opportunity to comment on FDA's regulation of OTC drugs, and, if there is time on the program, we would welcome the opportunity to speak.

There are several areas in which FDA's oversight of OTC drugs could be revised to provide for appropriate regulatory oversight, protection of public health, and improve access to and information about OTC drugs.

First, to address the questions FDA asked in their notice of meeting:

A. Criteria FDA should consider in deciding on OTC availability.

FDA will doubtless receive many discussions of clarity of labeling, long history of safe use, low toxicity of the active ingredient for its intended use, potential for misuse, etc. These are the traditional criteria FDA has used for a long time. BD would like to suggest that FDA also consider the intended user of the product in developing criteria for OTC availability. As makers of both "professional use only" and "consumer" OTC products, BD is aware of the differences between these two customer groups, and a product that may present a risk for one group may present less of a risk for the other. Most OTC decisions are made with the consumer in mind. It might be worthwhile for FDA to consider a slightly different risk assessment for products for use only by health care professionals.

Additionally, FDA has asked if it should consider public health risks in determining whether or not to provide products as OTC. BD believes that public health should be a consideration in any safety assessment, but questions whether FDA, as it is currently staffed, can perform these assessments scientifically. The inquiry is one that requires skills and expertise different from that required for assessing a product's effect on the individual. The example given, concern that use of antimicrobial drugs will increase prevalence of resistant mutations, is an oversimplification that has generated more heat than light over the years. Its inclusion in this document is a matter of concern. The probability of an antimicrobial product generating a resistant mutation varies with the mechanism of antimicrobial action. For narrow spectrum, low-potency antimicrobial drugs, the potential for producing resistant species is fairly high. Even broad spectrum, high potency antimicrobial drugs that act by disrupting a single link in a metabolic chain

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have measurable potential for producing mutations. But use of other antimicrobial compounds, such as iodine or alcohol, produces a number of reactions, any one of which could inactivate the bacterium. In order to develop a mutation that would be resistant to alcohol, the bacterium would need to have a different type of cell membrane and a number of different enzymes, receptors, and regulators. Thus the probability of a successful mutation is so reduced as to be near zero, even with the high rate of bacterial reproduction. To summarize, BD supports consideration of public health in OTC decisions but believes that the decisions must be based on good science, including careful consideration of the intended user.

B. Classes of products

BD again urges FDA to consider the category of "professional use" products separately from "consumer use" OTC products.

C. Consumer understanding: BD believes that a single regulatory approach that could be optimal for consumers will not be optimal for professional users. For example, professional users are constrained by practice guidelines and hospital policy in their use of scrub products. Additionally, the user does not make the buying decision, usually; a hospital purchasing group makes this decision. This group will consider a number of variables besides the performance of the product in making their choice. The current OTC labeling regulations are designed explicitly for lay consumers of OTC products, and serve to increase the cost of professional use products without a commensurate increase in useful purchaser/user information.

In terms of consumer understanding of OTC drugs, we believe that FDA's new labeling requirement will assist lay consumers to compare products and should reduce misuse. Since self-medication is on the rise, FDA should increase its efforts in consumer education, especially by making Internet consumer education more easily available, and by publicizing what is already available on the CDER website in other media. One approach to testing understanding used successfully by some marketing companies is the website questionnaire. Customers "fill in the blanks" and responses are tabulated automatically. Feedback is instantaneous.

In terms of consumer understanding of home in vitro diagnostic tests, BD expects that DCLD, CDRH would take the lead in any educational efforts. Current FDA requirements address instructions for use understandable at the seventh grade level, and demonstration of performance comparable to that in a clinical laboratory.

D. Selection of treatment: If there are coexisting prescription and OTC therapies for the same disease, the indications for use, warnings or contraindications (or all three) must be different. These differences have to be made clear to the consuming public. FDA should make comparative indication, warning, and contraindication tables available on its website for such drugs.

E. Marketing: BD sells in many countries, and we believe that the FDA could learn from the marketing practice of other countries. Some products that are now not available OTC could become available if they could be sold without a prescription, but with a pharmacist's advice. We have pointed out that there already exist two ways of marketing OTC products in the US, professional and consumer. FDA has often regulated professional OTC using a consumer OTC paradigm. If a third category of OTC were to be developed, there would need to be a system to assure that all three are regulated individually.

F. Rx to OTC switch: FDA should continue to work with stakeholder groups to develop better and clearer guidance for prescription drug NDA sponsors to employ when seeking a switch, but should not take the decision to apply out of the hands of the NDA sponsor. If FDA chooses to switch a drug product over the objections of the sponsor, the sponsor is entitled to a hearing. FDA should also develop guidance on criteria to employ if an NDA amendment requesting a switch is to be considered for evaluation as a petition

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Other issues in the regulation of OTC

GMP: Drugs. Many OTC drugs are products with a long-standing history of safe manufacture. While FDA's formal position is that drug GMP per 21 CFR parts 210 and 211 represents a minimum expectation that includes OTC as well as prescription drugs, BD suggests that some expectations now a part of current GMP be reevaluated for OTC.

1. Absolute requirement for finished product testing. With the continuing emphasis on validation of manufacturing processes, it is conceivable that parametric release could provide better assurance of product consistency than finished product testing does. This is especially true for extremely well characterized processing operations. We believe that FDA should look at this requirement in the light of current chemical engineering practice for high-purity formulations and pilot a program comparing results of parametric release with finished product testing.

2. "Appropriate intervals" for validation of a vendor's C of A. If a component vendor has a suitable Quality Agreement with a manufacturer, and the vendor is audited periodically, an appropriate interval could be whenever the vendor changes his process, not annually, as is now expected.

3. Validation of test methods: Many non-compendial methods have wide acceptance, such as those developed by ASTM. FDA should agree that some non-compendial standard methods do not require additional validation by the laboratory using them.

Monograph completion:

The monograph process is still cumbersome and the length of time required for finalizing a monograph makes it almost certain that the monograph will not represent the most current science by the time it is published. As an example, Congress required the completion of the sunscreen monograph in its 1997 amendment of the FDC law. The monograph, although published as a final regulation, is still not effective, because of certain unresolved issues. We appreciate FDA's willingness to work with stakeholders in improving and streamlining this process, but believe more emphasis should be placed on timeliness of resolution.

Finally, we want to commend FDA for holding this meeting. OTC drugs affect more individuals than do prescription drugs. They reach a wide consumer base, and that base is increasing as more and more Americans opt for self-medication. As the cost of prescription drugs escalates, the availability of safe effective non-prescription drugs becomes of greater and greater importance to our National Health. FDA is recognizing this need by their increased attention to this important subject.

Sincerely



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