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February 17, 2001

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

RE: [DOCID: fr19de00-70] Comments on Draft Guidance for Submitting Requests for Exemptions and Deferrals on Labeling OTC Human Drug Products

To Whom It May Concern:

I suggest that the Food and Drug Administration ("FDA") withdraw the draft guidance document available to the industry that aids manufacturers, distributors, and packers in avoiding the new over-the-counter ("OTC") drug labeling requirements. The draft document renders additional information on the process of obtaining an exemption or deferral from the final rule establishing a standardized format and contents requirements for the labeling of all OTC drug products. I feel that the document is inappropriate because it is contrary to public policy, goes against the responsibility of the FDA, overlooks the fact the OTC drugs are easily accessible to public, and defeats the purpose of the new labeling law.

The document should be withdrawn because public policy demands that the Agency should not grant any additional concessions to drug manufacturers when public health and safety are at issue. It does not send a good message to the public when the FDA drafts guidance that elaborates on procedures to evade the requirements of substances that are so potentially dangerous to consumers. The draft guidance was most likely written because the FDA estimates

that changing the labeling on nonprescription drugs will cost drug companies about $58 million. The Food and Drug Administration should demonstrate to the public that consumer health should not be sacrificed for the pockets of the manufacturers, packers, and distributors.

Also, draft guidance in and of itself, is inherently confusing even to the informed consumer. Draft guidance, like the one referred to in this letter, is a document prepared for FDA staff, applicants/ sponsors, and the public that describe the Agency's interpretation of or policy on a regulatory issue. The guidance documents do not establish legally enforceable rights or responsibilities, nor do they legally bind the public or FDA. The guidance documents solely reflect the agency's current thinking. However, FDA employees may only depart from guidance documents with appropriate justification and supervisory concurrence. (See 21 CFR 10.115) To the consumer, it is ironic that the FDA is not legally bound by the draft guidance, but yet and still, an FDA employee must have approval to defer from it. This contributes to the guidance document appearing more like a law, which would defeat public policy by giving the consumer a negative perspective of the FDA because it seems as if the Agency is developing law contrary to the welfare of the public.

Nonetheless, this "guidance" further elaborates on 21 CFR 201.66(e), which allows a manufacturer, packer, or distributor to be exempted or deferred from using the new standardized OTC drug labeling format on the basis that the requirement is "inapplicable, impracticable, or contrary to public health or safety." This is a difficult threshold for a drug producer to meet, but justly so, because public health and safety are at stake. The draft guidance in issue addresses concerns that are encountered when applicants endure the exemption and deferral process, such as procedure, turn-around time, ways to expedite the process, standards of review, appeal process, and trade secret violations.

It is the duty of the FDA to enforce laws enacted by Congress and also uphold their own regulations to "protect the consumer's health, safety, and pocketbook." The FDA is to enforce laws that regulate foods, drugs and medical devices for humans or animals, cosmetics, and electric products that emit radiation. The FDA also must ensure that all labeling and packing is in English, truthful, informative, and not deceptive. However, one of the FDA's primary concerns is to ensure that consumers can purchase safe and effective medication. This criterion will not be met if the draft guidance is not withdrawn.

The draft guidance referencing exemption and deferral from labeling guidelines should be withdrawn because public health and safety are at issue when over-the-counter drugs are easily accessible to the general public without easily intelligible warnings and directions. An over-the-counter drug is more accessible to the consumer than any other drug, and therefore, more dangerous than all other drugs. The package labeling must bear adequate directions and warnings and not be false or misleading. Since 1972, prescription drugs have become available over-the-counter at a rate of two or three a year. Currently, there are about 100,000 over-the-counter drugs for sale in the United States. Americans buy about 5 billion over-the-counter drugs each year and everyday, people unknowingly misuse OTC drugs. Also, in the United States, over 170,000 people are admitted to the hospital every year because they misused an over-the-counter product. Studies have suggested that over half of these cases could have been prevented with better information and consumer education.

Consumers are relying more heavily on self-diagnosis and assuming a greater responsibility for their own health. As more and more drugs become available over-the counter and used without medical supervision, it is imperative that consumers are provided with labels that are easy to read and understand. The information on the label of an OTC drug is most likely

the only information a consumer will receive regarding the proper use of the medication and any safety warnings.

Over-the-counter drugs should be taken using the same precautions as prescription drugs. Special care is necessary if more than one of these products is used at the same time, or if an OTC product is taken in conjunction with a prescription product. There also are some OTC drugs that shouldn't be taken by persons with certain medical conditions. For all of these reasons, over-the-counter drugs are potentially very dangerous to consumers.

Even Peter Rheinstein, M.D., director of the medicine staff in the FDA's office of Health Affairs, says, "Just because something is sold over the counter doesn't mean it's absolutely safe. Any medicine that's strong enough to help you also has the power to hurt you if you don't take it right."

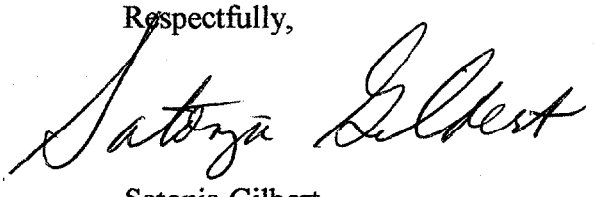
On March 17, 1999, the FDA published a final rule in the Federal Register that established the standardized format and content requirements for the labeling of all OTC drugs. This rule is intended to standardize labeling for all OTC human drug products to further the consumers' safe and effective use of these products by making labels easier to read and understand.

Drug labels were formerly confusing and hard to read, but the new drug labels rectify these problems. The new uniform label will have a minimum size font; be divided into categories such as active ingredients and amounts, doses, purposes, contraindications, warnings, and directions; and be in plain English. The FDA labeling requirements pre-empt state and local rules that outline different or additional format and content requirements. The new labels will start to appear in the next two to six years. So, manufacturers have a chance to change their labels and sell their current stock.

The goal of the uniform label is to kelp consumers understand a nonprescription drug's benefits and risks and take the medicine correctly. Using very stringent requirements when determining whether to exempt or defer an OTC drug from the new labeling standard should fulfill this goal. Instead, the draft guidance defeats the purpose of the new labeling statute by giving producers a "way out".

The then Vice President, Al Gore, announced on March 11, 1999, that the standardized OTC drug label will "ensure that the labels on medicine we buy over-the-counter are no longer written in language that is over our heads. Starting here and now, when children wake up sick in the middle of the night, parents won't have to read a dictionary to read the directions. And people won't need a magnifying glass to find out what's in their medicine." For all of the reasons stated, it is only proper for the FDA to bring these words to life by withdrawing this draft guidance and ensuring that only the stringent requirements of the law govern which potentially dangerous drugs are exempted or obtain deferral from the new labeling standard. Only by this withdrawal will the FDA fulfill its long-standing duty to "protect the consumers' health, safety, and pocketbook."

Respectfully,



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