



DEC 21 2001

McNeil Consumer Healthcare
Attention: Paula J. Oliver
Senior Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034-2299

RE: Docket No. 98N-0337
Applications for Exemption
APP 28, 29, and 33 through 37

Dear Ms. Oliver:

We are responding to your applications for exemption (APP) 28 and 29, dated July 24, 2001, and APP 33 through 37, dated November 27, 2001, requesting a deferral of the compliance time for implementation of the Drug Facts labeling requirements in 21 CFR 201.66(c) and (d) for the following over-the-counter (OTC) drug products:

<u>Application No.</u>	<u>NDA No.</u>	<u>Product</u>
APP28	None	Tylenol Caplets Extra Strength 10 count vial
APP29	None	Tylenol PM Caplets Extra Strength 10 count vial
APP33	19-012	Motrin IB Caplet 2 count pouch
APP34	None	Tylenol Sinus Geltab 2 count pouch
APP35	None	Tylenol PM Gelcaps 2 count pouch
APP36	None	Tylenol Sinus Caplet 2 count pouch
APP37	19-860	Imodium AD Caplet 2 count pouch

You mentioned the limited amount of space that is available for labeling on these shelf keeping units. In APP 28 and 29, you requested a deferral of 8 months beyond the May 16, 2002, compliance date to implement a new wrap-around label for these Tylenol products. In APP 33 through 37, you requested a deferral of 6 months beyond the May 16, 2002, compliance date to implement a new booklet style pouch to accommodate implementation of the new Drug Facts labeling requirements. You stated that your company needs these deferrals to acquire, install, and validate the equipment necessary to produce a compliant wrap-around label and booklet pouch package on a reliable, repetitive basis. You indicated that the wrap-around label, the pouch, and the equipment are innovative technologies that require sufficient development time to master the interface between equipment and material. You provided a projected timeline for implementation of the label and pouch.

All of the deferral requests indicated that the company would start to ship new product in the 4th quarter of 2002. On December 13, 2001, in a telephone conversation with Mr. Gerald Rachanow of our division, you amended the deferral time for APP 28 and 29 from 8 to 6 months.

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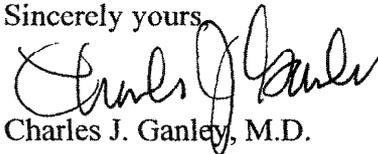
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You also stated in APP 28 and 29 that the company's proposed timeline was based on FDA approval of the wrap-around vial label submitted as a pre-approval SNDA under NDA 19-012. As you are aware, FDA approved the SNDA on September 7, 2001. Therefore, label design issues should not prolong the company's timeline.

For the reasons provided in your applications, the agency is, as a matter of enforcement discretion, granting your company's requests for a deferral from the "Drug Facts" labeling requirements in 21 CFR 201.66. We intend to exercise enforcement discretion for the products identified in APP 28, 29, and 33 through 37 for a period of 6 months after May 16, 2002. At the end of this deferral period (i.e., November 16, 2002), the labeling for all of these products must comply with the requirements of 21 CFR 201.66 at the time the products are initially introduced or initially delivered for introduction into interstate commerce.

If you have any comments or questions regarding these deferrals, please reference the docket and application for exemption numbers and submit them to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. I hope this information is helpful.

Sincerely yours,



Charles J. Ganley, M.D.

Director

Division of OTC Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research