

September 15, 1999



Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

1629 '99 SEP 21 01:49

APPLICATION FOR EXEMPTION

**Re: Request for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Docket Number 98N-0337**

**Subject: Zee Medical, Inc.
PainAid® Pain Relief Tablets (#1417, 1418, 1419)**

This is a request for exemption from 21 CFR 201.66(c)(8), the requirement for listing the inactive ingredients on the OTC drug label, for Zee Medical, Inc. PainAid® Pain Relief tablets. We believe this requirement is impracticable for our method of manufacturing and distribution due to the factors outlined below. We are requesting to be allowed to use the phrase "may contain" to list inactive ingredients that may or may not be present in the product.

Confidentiality

We request that the information in this document be kept confidential to the fullest extent possible, particularly information concerning the financial impact of this request on our company.

Overview of Zee Medical, Inc.

Zee Medical, Inc. is a wholesale distributor of first aid and safety products. We provide these products to independent distributors and company-owned distributors who in turn sell them to employers for use in the employers' workplace first aid cabinets. These products are delivered to the employer by means of a van-based delivery system.

Description of Product

PainAid® Pain Relief tablets are OTC pain reliever/fever reducer tablets packaged in sealed unit dose packets (2 tablets per packet). The packets are then packaged into dispenser boxes of 100, 250 or 1000 tablets each. The product is sold by our distributors to employers for use in workplace first aid cabinets, also supplied by Zee Medical. This product and other products of our OTC tablet line comprise the largest and most important segment of our business.

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Manufacturing/Distribution Process

Our company purchases the finished tablets in bulk form, then repackages the tablets into the unit dose packets and dispenser boxes bearing our label. In order to (1) ensure an uninterrupted supply of bulk tablets, (2) prevent short term emergencies at our suppliers from affecting our production schedule and (3) keep our costs under control, it is essential that we have multiple suppliers for the bulk tablets. We currently have three suppliers for the bulk PainAid® Tablets. Although the active ingredients are identical, the inactive ingredients vary from supplier to supplier. Due to this variation, we have not listed any inactive ingredients on the label in the past.

Reasons for Exemption Request

As indicated above, PainAid® tablets together with the other products of our OTC tablet line comprise the largest and most important segment of our business. Any significant reduction in the profitability of these products would cause serious consequences for our company. If we are required to list the inactive ingredients on the dispenser box, we will be forced into one of three alternatives: (1) purchase the bulk tablets from only one supplier, (2) carry separate inventories of dispenser boxes for each supplier's tablets, or (3) require our bulk tablet suppliers to manufacture the tablets to our exact formula. Each of these alternatives is discussed below.

Alternative 1 - Purchase tablets from only one supplier. This is a practice that we have strictly forbidden for many years. With only one supplier, we would run the risk of having no product available during situations where the supplier is experiencing production difficulties. In fact, this very thing happened to us several years ago, which led to a disastrous situation where we were unable to obtain the product for a period of 8 months. As a result, we have established a firm policy that we will always have more than one approved supplier for our bulk tablets.

Alternative 2 - Carry separate inventories of packaging and labeling materials for multiple suppliers of the same product. We have evaluated this from an operations standpoint and have determined that we do not have the capability to carry separate and distinct inventories of two or three versions of the same box or label for each product in our tablet line. Aside from the logistics of the increased warehouse space required to store the new materials, the establishment of new SKU's and inventory controls, and the revision of all supporting documentation (batch records product specifications, bill of materials), there would be the increased threat of labeling mixups and the increased burden of having to triple our efforts for every new FDA labeling requirement. The burden of this would cripple our operation.

Alternative 3 - Require different tablet suppliers to manufacture to the same formula. We have explored this option with our suppliers and have determined that this is impracticable. Each manufacturer has different blending, granulating and tablet compressing equipment; different raw material sources; and different expertise in compounding and processing these materials. A change to a formula with which they do not have experience would, at the very least, be time consuming and expensive. At worst, it could also lead to production problems, delays, and inferior tablet quality.

Exemption Request

We are requesting exemption for this product from 21 CFR 201.66(c)(8), which requires listing the inactive ingredients on the OTC drug label. We note that many OTC drug labels currently use the phrase "May also contain [list of ingredients]" to describe ingredients that may or may not be present in the formula. We request that we be allowed to make the following statement to convey inactive ingredients that may be present in PainAid® Tablets:

Inactive ingredients may contain cellulose, corn starch, croscarmellose sodium, D&C yellow #10, FD&C yellow #6, magnesium stearate, polyvinylpyrrolidone, silicon dioxide, sodium meta bisulfate, sodium starch glycolate, starch, stearic acid.

The label for this product will meet all other requirements of 21 CFR 201.66.

We appreciate your consideration of this request and look forward to receiving your response as soon as possible. If you need additional information or would like to discuss this matter in person, please call me directly at (949) 252-9530.

Very truly yours,



Kevin Lloyd
Manager, Quality and Regulatory Affairs
Zee Medical, Inc.



Zee Medical, Inc.

FAX TRANSMISSION

To:	Ms. Jenny Butler	From:	Kevin Lloyd
Of:	Food and Drug Administration	Company:	Zee Medical, Inc.
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Date:	October 14, 1999	Fax No:	949-252-9527
Pages:	1	Phone No:	949-252-9530

This is in reference to our Application for Exemption from certain requirements of 21 CFR 201.66 (OTC Labeling Format), Docket Number 98N-037, for Zee Medical PainAid Pain Relief Tablets. The Application for Exemption is dated September 15, 1999.

As you indicated during our telephone conversation today, the application includes a section requesting that the submitted information be kept confidential to the extent possible, however, in order for FDA to consider the application, Zee Medical must allow the information to be released publicly.

Please accept this as authorization for FDA to publicly release the information contained in the Application for Exemption referenced above.

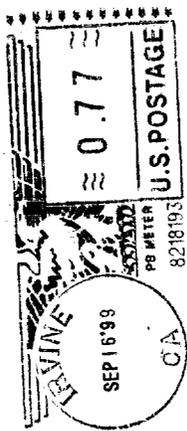
If you need additional information, please contact me 949-252-9530.

Sincerely,



Kevin Lloyd
Manager, Regulatory Affairs
Zee Medical, Inc.

PAISSORTED
FIRST CLASS



AMERICA'S
WORKPLACE
SAFETY
EXPERT.

ZEE SERVICE, INC.

A MCKESSON COMPANY

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Attn: Request for Exemption from
21 CFR 201.66 (OTC Labeling Format)
Docket Number 98N-0337