

QUALIS INC.

4600 park ave.  
des moines, iowa 50321  
515-243-3000  
fax 515-282-1417

5461 '02 AUG 12 A9:22

August 8, 2002

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

Re: Docket No. 02N-0058: Pediculicide Drug Products for Over-the-Counter Human Use

Dear Sir or Madam:

The following comments are being forward regarding the Food and Drug Administration proposed Federal Register announcement May 10, 2002 to amend the final monograph for OTC pediculicide drug products. Such revisions will require changes in the labeling of the products for statement of identity, warnings, directions, and other required statement for consumer use. The FDA states two reasons for the proposed amendment: to make pediculicide drug products labels conform with the proposed new labeling content, format, and to increase the probability of treatment success.

Our comments specific to changes in label content, identity, warnings, directions and other required statements have been forwarded to CHPA, Consumer Healthcare Products Association for inclusion in their response. CHPA is a national association representing manufacturers and distributors of OTC drug products and dietary supplements. In response to this announcement, CHPA organized a task force of members who manufacture and market pediculicide products. This task force represented both brand and private label entities. As such, the comments submitted by CHPA represent issues that have parity whether the product is manufactured by a large branded company or a smaller private label company.

The following comments address specific issues for private label manufacturers of pediculicide.

In reading through the FDA's comments and analysis of economic impact, it is not clear if this information is current or was conducted in prior years for the new drug label format, which had a sunset of May 2002.

The FDA references 23 manufactures, 36 marketers, and approximately 75 SKU (Stocking Units) – or individual products, package, and sizes. The agency further indicates that the one-time cost to industry is approximately \$3,000 to \$4,000 per SKU and estimates actual costs to be lower since "private label small manufacturers use simpler and less expensive labeling". The agency also infers that these changes will cost less than 1 percent of any manufacturer's total sales. The FDA proposed that an 18-month sunset for conversion of inventory stock to the new labeling is reasonable and can be concluded in the "normal" course of business.

~~02N-0058~~ 02N-0058

CZ

We are a small private label OTC manufacturing company, yet represent the single largest private label manufacturer in the U.S. for pediculicide products.

Similar to brands, we have several formulations that we market to the retail trade in different unit sizes and "combo" packs. Since the branded product is sold under a single brand name, the number of stocking units (SKU) that a brand must convert in comparison to private label is minimal, estimated no greater than 7 SKU. Since each SKU has a unit label, folding carton, and an insert, a branded company will be required to convert an estimated 27 component parts during the 18-month horizon.

Each private label SKU unit label and folding carton is unique to a specific distributor or retailer. As such, our organization will be required to convert 196 SKU and 396 component parts within an 18-month horizon under the proposed amendment. Only insert material is generic to all SKUs.

While these are regulatory changes, distributors and retailers require that any change to private label under their store brand be submitted for their approval and coordinated with their respective graphic agency prior to actual printing of the component. Samples from the initial component print is, in many cases, required to be re-submitted for approval prior to use. This review process is in addition to our internal regulatory and document control review of each component part.

Given the logistical coordination to revise 396 components and subsequent coordination of these activities with numerous graphic agencies, distributor/retailer approval processes, and coordination of component fabrication before inventory conversion can commence, we request that the FDA provide a 24-month revision horizon from the date of final amendment in lieu of the proposed 18 months.

The agency indicates that the one-time cost to industry is approximately \$3,000 to \$4,000 per SKU and estimates actual costs to be lower since "private label small manufacturers use simpler and less expensive labeling".

Given the evolution of private label and current retailers' strategy to position their private label product lines as "brands", the corresponding graphic design, quality and costs have also risen in parity with national brands. Private label revision costs are significantly higher than brand company costs due to unique retailer graphics and subsequent number of component parts to be revised. These costs are absorbed by the private label manufacturer.

Therefore, while the agency infers that costs will represent less than 1 percent of total gross sales of all products sold by any company, the relationship of costs to gross sale of pediculicide products for private label is at a substantial higher cost than a branded company. Estimated 27 components for a brand company compared to 396 components for a private label company.

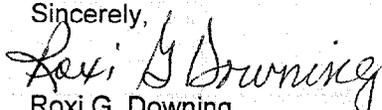
These costs have been incurred in the past 18 months to comply with the drug labeling format that had a sunset of May, 2002. The proposed amendment will require industry to incur these costs again over a near term 18-month horizon. As such, this lends to a greater disparity of costs and economic impact to a private label company as compared to a national brand company.

Once all of the graphic, approval coordination, and regulatory/document control review process is completed, actual inventory conversion can be done within a relative short period of time. Thus, conversion or the sell through of former stock and integration of new stock is not the issue. However, the front-end logistical coordination described above is a primary issue. Spreading the costs and economic impact over a longer period of time is second.

Our comments are not intended to discourage the Food and Drug Administration from initiating these changes. Our company supports the FDA's mission to provide consumers appropriate treatment information, conformity of labeling format, and increase the probability of treatment success. However, we do urge the agency to provide private label manufacturers adequate logistical and economic sunset of a minimal 24 months in lieu of the proposed 18 month sunset.

Should have any questions, please feel free to contact me.

Sincerely,



Roxi G. Downing  
Chairman/CEO

**FedEx** USA Airbill  
Express

FedEx  
Tracking  
Number

834183238903

Form  
I.D. No.

0215

Recipient's Copy

RECIPIENT: PEEL HERE

**1 From** This portion can be removed for Recipient's records.

Date 8/10/02 FedEx Tracking Number 834183238903

Sender's Name Roxi Downing Phone 515 243-3000

Company QUALIS INC

Address 4600 PARK AVE Dept./Floor/Suite/Room

City DES MOINES State IA ZIP 50321

**2 Your Internal Billing Reference**

**3 To** Recipient's Name Document Management Bank (HFA-305) Phone

Company Food and Drug Administration

Address 5630 Fisher Ln, Rm 1061 We cannot deliver to P.O. boxes or P.O. ZIP codes.

Address Dept./Floor/Suite/Room

City Rockville State MD ZIP 20852



**4a Express Package Service**

FedEx Priority Overnight Next business morning  
 FedEx Standard Overnight Next business afternoon  
 FedEx First Overnight Earliest next business morning delivery to select locations  
 FedEx 2Day Second business day  
 FedEx Express Saver Third business day  
FedEx Envelope rate not available. Minimum charge: One-pound rate

**4b Express Freight Service**

FedEx 1Day Freight\* Next business day  
 FedEx 2Day Freight Second business day  
 FedEx 3Day Freight Third business day

\* Call for Confirmation.

**5 Packaging**

FedEx Envelope\*  
 FedEx Pak\* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak  
 Other

**6 Special Handling**

SATURDAY Delivery Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes  
 HOLD Weekday at FedEx Location Not available for FedEx First Overnight  
 HOLD Saturday at FedEx Location Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods?

One box must be checked.  
 No  
 Yes As per attached Shipper's Declaration  
 Yes Shipper's Declaration not required  
 Dry Ice Dry Ice, 9, UN 1845 x \_\_\_\_\_ kg  
Dangerous Goods (including Dry Ice) cannot be shipped in FedEx packaging.  Cargo Aircraft Only

**7 Payment Bill to:**

Enter FedEx Acct. No. or Credit Card No. below.  
 Sender Acct. No. in Section 1 will be billed.  
 Recipient  Third Party  Credit Card  Cash/Check

Total Packages	Total Weight	Total Charges
1		
		Credit Card Auth.

\*Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

**8 Release Signature** Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.  
Questions? Visit our Web site at [fedex.com](http://fedex.com)  
or call 1.800.Go.FedEx.® 800.463.3339.

Rev. Date 10/01 • Part #1575100 • ©1994-2001 FedEx • PRINTED IN U.S.A. GBFE 102

447

0208316646