5-3-94

IRB BRANCH REVIEW - TSS

Record Number(s)

D199654
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2/22/94
IN 3/23/94 OUT 5/3/94

EFFICACY

FILE OR REG. NO. 64439-R

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 2/I/94, 3/7/94, 3/21/94, and others

DATE OF SUBMISSION 12/7/93, 1/15/94, 3/7/94?, 3/21/94

DATE SUBMISSION ACCEPTED 2/22/94, 3/23/94

TYPE PRODUCTS(S): I, D, H, F, N, R^{X}, S

DATA ACCESSION NO(S). 431216-04

PRODUCT MGR. NO. 14

PRODUCT NAME(S) MOLE-MED MOLE REPELLANT AMD LAWN PROTECTION

COMPANY NAME Mole-Med

SUBMISSION PURPOSE registration, support claims

CHEMICAL & FORMULATION 66% Castor Oil and [redacted]

liquid

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Efficacy Review: MOLE MED MOLE REPELLANT [sic] AND LAWN PROTECTION, 64439-R
Mole-Med
Aurora, IN 47001

200.0 INTRODUCTION

INERT INGREDIENT INFORMATION IS NOT INCLUDED

200.1 Uses

A 66% Oil of Ricinus (Castor Oil) and [redacted] liquid mixture proposed for registration as a "REPELLANT" to be used "for repelling Eastern moles and Townsend's moles from lawns."

200.2 Background Information

See efficacy reviews of 6/19/90, 4/30/91, and 2/25/93, along with other information in product's jacket, and information in brown folder prepared by Daniel B. Peacock to track legal actions pertaining to this product.

The material routed for my review consists of proposed labels submitted on 12/7/93, 1/15/94, and sometime on or before 3/7/94, a report of a somewhat curtailed efficacy study submitted on 1/15/94, a "FAXed" submission of 3/21/94 which includes what is alleged to be the seminal document that inspired the development of this products and some testimonial letters, and a collection of reports of telephone conversations and "FAXes" involving various parties and bearing various dates. The "FAX" of 3/21/94 came from Eldon Pickett of MOLE-MED. The labels, the efficacy studies, and at least one "FAX" came from Pickett's consultant, Dr. Kenneth P. Reed. The cover sheet to the material "FAXed" by Reed includes a copy of a poem entitled "The Dinosaur," which goes on at length about how dinosaurs had anterior and posterior brains and have been extinct for millenia.

201.0 DATA SUMMARY

The efficacy report was assigned the MRID # 431216-04. The report was written by Glenn Dudderar and Dale Elshof of Michigan State University. The report consists of a page of narrative and two tables.

According to the report, the researchers identified 26 sites in Ingham County, MI (where the University is located). In early September of 1993, 12 of these sites were treated ("according to label directions") and were observed for signs of continuing mole activity on 1-6 occasions (the report is not clear on this point). The 14 untreated sites apparently were not monitored.

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As their account is short, I have decided to let the report of results by Dudderar and Elshof speak for itself:

> ". . . insufficient funding prevented all further treatment and limited observation of all treated sites. Of the nine treated sites that were observed, all showed an increase in mole tunneling activity . . . . Subsequent observations of seven of those sites made one and two weeks later showed no tunneling activity, and areas adjacent to two if the treated areas showed new mole activity. As of November 23, 1993, no mole activity is evident on these seven sites.
>
> While this preliminary study cannot link the ceased activity directly to product application, these promising results are similar to those of other field tests with a similar product conducted by Dudderar during 1988-89. Additional research is needed to account for the effects of weather, soil type, and irrigation."

The study cannot link the reported change in activity to treatment because mole activity in untreated areas was not monitored.

Actually, there should have been sham-treated areas as well as untreated areas to control for the possibility that the flooding of moles' burrow systems can act on its own as a control measure. I have used this method (with apparent success, but also lacking appropriate controls) on my own property. This approach is mentioned by Henderson in his chapter on mole control in the manual <u>Prevention and Control of Wildlife Damage</u> (U. of NE, Lincoln, 1983, pp. D-53 to D-61) as a way of driving moles to the surface (which did not happen in my experience) and suggests that flooding of lowlands "menaces the adult mole and its progeny." Henderson also mentions drying out soil and other means for reducing food supply as methods that can reduce mole numbers in an area, but cautions that

> ". . . before leaving the area, moles may increase their digging in search of food, thereby possibly increasing damage to turf and garden areas."

Henderson also lists "the castor bean" (probably meaning growing castor bean plants) among the "cure-alls" that are not supported by "known research."

The observations reported by Dudderar are not inconsistent with the notion that the product might have killed off some grubs and earthworms in the treated area. The account

suggests that moles increased their tunneling next to treated areas before signs of new mole activity ceased to be observed. Monitoring appropriate control sites could have indicated whether there were any seasonal effects on appearance of mole tunnels. Weather records should indicate when the first frost occurred, when the first snow occurred, and when the upper layer of ground might have frozen. Cold temperatures might drive worms lower in the soil, with the moles perhaps following the food source and going lower also to feed on other food items.

Before passing final judgment on the efforts of Dudderar and Elshof regarding MOLE-MED, I would like to see all of the records assembled in their curtailed study and any public reports that there might be concerning Dudderar's 1998-9 research "with a similar product." I also would like to speak with Dudderar about these studies. Because it is claimed that study was run according to EPA's "Good Laboratory Practice Standards" (GLPs, 40 CFR, §160), there should be ample records and a study protocol on file for the MOLE-MED research. (Several of the "FAXes" and phone messages pertained to getting Dudderar's and Elshof's signatures on a "GLP" page.)

On 3/24/94, I attempted to telephone Dudderar but, due to his absence, was able only to leave a message on his answering machine. I left another message on 3/25/94 and several others over the next few days. In April, I began to receive reply messages from Dudderar, whereupon I again started trying to call him. This game of answering machine tag continued for more than a month until Dudderar successfully reached me on 4/28/94.

Dudderar confirmed that there was no monitoring of untreated areas, although only parts of some sites were treated, and stated that the report cited above represents the sum total of information collected on MOLE-MED last Fall. He noted that the observations made were essentially qualitative (i.e., noting whether or not there was mole activity). He added that seasonal effects on moles' sub-surface digging probably were not significant as the study area experienced a warm Autumn (such that he would have expected to see mole activity up to Thanksgiving).

He also said that the increased mole activity in treated areas following MOLE-MED treatment looked much like that which is seen when some or all of the prey base is controlled with Diazinon and speculated that the immediate posttreatment increase in apparent mole activity would occur even if there were only one mole present. This increase was followed by an absence of subsequent mole activity in the treated area and new evidence of mole activity in a nearby area. At a site

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where only part of the area had been treated, he reported that evidence of new mole activity in the untreated area ceased after he killed a single eastern mole.

As for duration of effect, Dudderar noted that one of the four areas treated last Fall which are convenient for him to observe has evidence of new mole activity this Spring.

Dudderar said that he was not sure how the effect on moles was mediated. Regarding the comparison with Diazinon treatment, Dudderar and I discussed what effects MOLE-MED use might have on moles' prey. We discussed whether MOLE-MED might repel the prey, make them unpalatable, or kill them. If any such effects occur and are responsible for how moles respond to the treatment, MOLE-MED would be "repelling" moles indirectly, as a by-product of some other action.

Dudderar said that he has quite a bit of MOLE-MED left over from last Fall and that he has assigned some students to run new trials this Spring. These trials would include the monitoring of untreated areas. I suggested that he also try the spray material on earthworms to determine whether there were any obvious behavioral or physical effects. I also told him that he must respond truthfully on "GLP" pages in study reports (e.g., say the study was not done according to GLPs if it was not).

Regarding the 1988-1989 trials of another product, Dudderar said that he got similar results but added that the product did not smell (to him) much like MOLE-MED. He thought that the product had been abandoned by the company that was developing it, perhaps because of early negative feedback resulting from short-term posttreatment increases in mole activity.

Dudderar stated that he had tried castor plants with some effects on shallow tunneling in the summertime but that castor beans did not work by themselves.

If MOLE-MED does indeed move moles from one area to another nearby location and its effects in the original area wane over a fairly short period of time, neighbors in subdivisions might wind up playing a sort of slow mole ping-pong if they all were to use MOLE-MED when mole sign appeared on their properties. I wonder what the local sociological ramifications of such a game would be.

Of the various labels submitted, I have decided to focus upon the one that was received on 3/7/94. That label does not include the somewhat objectionable "Mole-Med is an old time way . . ." paragraph and includes detailed use directions. In the absence of conclusive research data, it does not make

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much sense to quibble about nuances of the use directions. The directions on the label received on 3/7/94 includes the statement

> "Mole activity increases temporarily as moles leave the treated area. "

This is an obvious allusion to the results reported by Dudderar and Elshof and, if these results are validated by 1994's research, a statement that must be on the label. It might have to be strengthened a bit.

My comments on the label received on 3/7/94 appear under "CONCLUSIONS."

The material which Pickett "FAXed" to EPA on 3/21/94 regarding the inspiration for the MOLE-MED product is interesting. It consists of three paragraphs attributed to page 320 (and probably 319, also) of the publication The Organic Way to Plant Protection, Rodale Press, Inc., Emmaus, PA (date not certain). The item attributes the following story to a Mrs. Frank Bjerstedt from Mentor, OH:

> "'I have heard that the castor oil plant had the ability to repel moles, but since we have young children, I didn't want to chance one of them getting at the beans. So, I purchased some castor oil and prepared an emulsion of the oil and liquid detergent in a blender, two ounces of oil to one of detergent, and whipped until it became as thick as shaving cream. I then added water equal in volume to the mixture and whipped again. Taking a regular garden sprinkling can, I filled it with warm water, added about two tablespoons of the oil mixture, stirred and immediately sprinkled it over the areas of heaviest mole infestation. Deeper soil penetration will be achieved if sprinkling can be done after a rain or a good watering.
>
> 'Result -- no moles, many worms, and a beautiful, lush mulched garden surrounded by a smooth lawn. I gave two treatments two weeks apart, but I suspect one would have been enough."

Mrs. Bjerstedt's recipe and dilution regimen are not very different from those proposed for MOLE-MED. Other than a possible desire to see her name in the magazine, Mrs. Bjerstedt would not have appeared to have reason to exaggerate the effectiveness of her castor oil/ detergent preparation as she was not seeking to market a product. If the publication as anywhere near as old (1910) as Pickett alleges, there would be little chance of finding Mrs.

Bjerstedt to ask for more information. (I would like to know more about the "many worms" comment, among other things.)

The testimonial items "FAXed" by Pickett read like most testimonials that I have seen for repellents (i.e., it works great; it's the best thing I've ever tried; and please send more if possible). MOLE-MED's latest testimonials have complaints about the products' being "taken off the market" added to them. Legally, the product never was on the market.

The basic problems with testimonials are that they could be written by anyone for any reason and that they are prepared by individuals who are not trained experimenters and who, perhaps despite all sincerity, could misinterpret the results of treatment. Occasionally, a testimonial letter describes an actual experimental effort which includes appropriate controls. I take such accounts more seriously than I do the typical testimonial.

202.0 CONCLUSIONS

1. The research report by Dudderar and Elshof states that the study was greatly curtailed due to limited funding. As no monitoring of mole activity in untreated areas took place, we concur with the authors that the

   "study cannot link ceased activity directly to product application."

   On April 28, 1994, Dr. Dudderar informed a member of my staff that he has students conducting additional trials with MOLE-MED this Spring and that these studies were expected to be completed within a month. As these trials would include the monitoring of untreated areas, they would seem to be designed better than the study run in 1993. We feel that at least some sham-treated (water only) areas should be monitored as flooding is occasionally mentioned as a method for controlling (or moving) voles. We also have suggested that small tests of the effects of MOLE-MED on earthworms and other prey be run to indicate whether the product's claimed effects on moles could be mediated indirectly.

2. The "DIRECTIONS FOR USE" on copies of the revised proposed label that we received on March 7, 1994, appear to be adequate, given our current limited knowledge about the effectiveness of the product. If Dudderar's and Elshof's accounts of how the product works are accurate, a statement regarding short-term increases in mole activity certainly would be necessary. It is possible that the results of the studies which Dudderar says are underway at this time will indicate that the proposed use

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directions should be modified somewhat.

3. Several other changes that are needed in other portions of the label received on March 7, 1994. These changes are listed below;

   a. At the top of the right column, delete

      "For repelling moles on lawns

      SHAKE WELL BEFORE USING".

      The messages conveyed by this text appear elsewhere on the label, and the "SHAKE WELL BEFORE USING" statement inappropriately obscures the heading "PRECAUTIONARY STATEMENTS." Deleting the text as indicated also will provide more space on the right panel. This added space will permit appropriate enlarging of the headings for "PRECAUTIONARY STATEMENTS," "DIRECTIONS FOR USE," and "STORAGE AND DISPOSAL." These headings should be in the largest type size that appears on the panel. The heading for "STORAGE AND DISPOSAL" must be centered so that it is parallel to "PRECAUTIONARY STATEMENTS" and "DIRECTIONS FOR USE" and is clearly superior to "STORAGE," "PESTICIDE DISPOSAL," and "CONTAINER DISPOSAL."

   b. Change the beginning of the "**WARNING:**" paragraph so that it begins with a complete sentence. The first sentence should read something like

      "This product can cause substantial but temporary eye injury."

      [NOTE TO PM: Check all precautionary text for accuracy and appropriateness. The item mentioned above was something that jumped out at me as I was scanning the label to look for claims and out-of-place use directions.]

   c. Change "REPELLANT" to "REPELLENT" in the name of the product. The "e" form is the preferred spelling and is the spelling used in pesticide regulation. While you certainly are free to spell it either way in the name of your product, we feel that misspellings other than obviously deliberate "cutesy-pie" renditions (e.g., "KILLZEM" instead of "KILLS THEM") and less preferred spellings may reflect negatively on the product and its

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manufacturer and undermine the degree of attention paid to the label as a whole.

4. The item "FAXed" to us on March 21, 1994, concerning the source of inspiration for this product was interesting. If this approach truly has merit for mole control, as Mrs. Bjerstedt reported, it should be possible to demonstrate the extent and duration of such effects in appropriately designed research studies.

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
May 3, 1994

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