

Deborah A. Chadbourne, L.L.C.

Attorney-at-Law

June 22, 2010

Original Sent by Courier

Electronic Copy Sent to Richard Keigwin and Monica Wait

Document Processing Desk (7508P)
US Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Richard P. Keigwin, Jr.
Director, Pesticide Re-evaluation Division (7508P)

Re: Propoxur Pet Collars
Sergeant's Pet Care Products, Inc.
Wellmark International

Dear Mr. Keigwin:

On behalf of Sergeant's Pet Care Products, Inc. ("Sergeant's") and with the approval and consent of Wellmark International ("Wellmark"), please consider this letter in response to the Agency's letter of April 19, 2010, and the PRD's representative's email of June 17, 2010¹. Those communications and this response concern Sergeant's pet collars registered under numbers 2517-61 and 2517-78 and Wellmark's pet collars registered under numbers 2724-454, 2724-275, 2724-491, and 2725-493 (jointly referred to as "Propoxur Pet Collars" or "Pet Collars"). For the reasons set out below, Sergeant's and Wellmark strongly object to the Agency's stated intention to publish the April 7, 2010, Agency report "Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars" ("2010 ORE"). Further, the Agency's request for voluntary mitigation measures which "would limit the availability of the product while studies are being conducted"² ("Stop Sale Mitigation") is without basis in fact or law. Both the publication of the 2010 ORE and implementation of the mitigation measures "envisioned" by the Agency would seriously damage, if not destroy, the market for the Propoxur Pet Collars.

We understand that the Agency³ intends to promptly publish the 2010 ORE in conjunction with the Agency's Final Work Plan for propoxur by posting these documents to the Propoxur Docket #0806. The precise date of such intended publication is unknown to us, but we have been led to believe that the date is imminent.

Because of the potential damage which may occur as a result of the publication of the 2010 ORE, please consider this letter in request for (1) a meeting with Sergeant's and Wellmark personnel to discuss this matter and its implications as soon as possible, and

¹ Monica Wait email of 6/17/2010 to James McFadden of Central Life Sciences and Kelly Hoskins of Sergeant's ("Wait email")

² Ibid., last paragraph.

³ From the Wait email and conversations with Ms. Wait, Tracy Perry and Michael Goodis during a conference call of 6/9/2010

(2) postponement of the imminent publication of the 2010 ORE. As will be described below, Sergeant's will be providing a report to the Agency this week which identifies significant concerns with the 2010 ORE and alternative risk calculations which should substantially reduce the Agency's concern. In addition, in order to provide the Agency with information regarding the consequences of the Stop Sale Mitigation measures currently envisioned, please consider this letter as our request to address mitigation issues during the above requested meeting.

Sergeant's is eager to resolve this matter without resort to legal action. We appreciate the Agency's difficulty in scheduling meetings on short notice and are prepared to accommodate the Agency's schedule for this requested meeting. Please contact the undersigned at your earliest convenience regarding scheduling.

Background

By Federal Register notice of December 16, 2009, the Agency established and opened for comment the Propoxur Docket #EPA-HQ-OPP-2009-0806 ("Docket 0806"). Such notice stated that "EPA is initiating its reviews of the pesticides identified in this document pursuant to section 3(g) of [FIFRA] and the Procedural Regulations for Registration Review at 40 CFR Part 155, subpart C...."⁴ Docket 0806 contained a number of documents, including a Propoxur Summary Document Registration Review: Initial Docket December 2009 ("Docket Initial Summary") which provided a Preliminary Work Plan ("PWP") and Fact Sheet. The Docket Initial Summary "summarize[s] the [EPA]'s current position based on the following documents⁵:...2. Propoxur: Registration Review Scoping Document for Human Health Assessments, November 17, 2009 (the "Scoping Document")."⁶ The Scoping Document stated that the "Health Effects Division (HED) Registration Review Team has evaluated the status of the human health assessments for the N-methyl carbamate (NMC) insecticide propoxur to determine the scope of work necessary to support Registration Review."⁷ The Scoping Document was quite clear in stating that an immunotoxicity study and Comparative Cholinesterase Assay ("CCA") study would be required and that "once these studies are made available to the Agency, they will be reviewed and HED will re-evaluate the points of departure and uncertainty factors for the risk assessment."⁸ The PWP contained an estimated timeline for completion of the propoxur registration review and listed, among several items, an estimated date for completion of the Final Work Plan of May 2010, issuance of a Data Call-In ("DCI") in January - March 2011, data submission in January - March 2013 and opening of a public comment period for review of the Preliminary Risk Assessment in July - September 2014."⁹

The comment period for Docket 0806 closed February 16, 2010. Within this comment period, comments were submitted by NRDC¹⁰ and MGK; only the NRDC comments are applicable to Pet Collars. The NRDC Comments question the adequacy of the residential post-application exposure assessments for Propoxur Pet Collars and requests "at a minimum,... that

⁴ 74 Fed. Reg. 66647-66648 (December 16, 2009)

⁵ There were 5 documents listed; the second document is discussed in this section and the fifth document is discussed in the section titled "Lack of Agency Basis for Stop Sale Mitigation Measures".

⁶ Initial Docket Summary page 3

⁷ Scoping Document, page 1

⁸ Scoping Document page 2

⁹ Initial Docket Summary, page 8

¹⁰ NRDC Comments dated February 16, 2010

EPA ... conduct residue testing for pet collars to obtain realistic estimates for residues, rather than rely on its faulty assumptions.”¹¹ The NRDC further requested that the Agency “include the exposure from indirect hand-to-mouth activity where an individual touches an object or food with pesticide-contaminated hands, and then puts that object or food into his or her mouth.”¹²

Contrary to the PWP and Initial Scoping Document for Docket 0806, the Agency conducted an Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars, summarizing the results in a memorandum dated April 7, 2010¹³ (“2010 ORE”). Sergeant’s was provided a copy of the 2010 ORE by letter from the Agency dated April 19, 2010. This letter states that the Agency conducted this 2010 ORE in preparation for response to the NRDC’s petition to cancel Propoxur Pet Pollars; the letter also refers to the 1997 Propoxur Reregistration Eligibility Decision (RED) and the Revised N-methyl Carbamate Cumulative Risk Assessment of 2007. This letter summarized the results of the 2010 ORE as calculating the margins of exposure (MOEs) for Sergeant’s and Wellmark’s products for residential post-application incidental oral (hand-to-mouth) exposure for children at 20 to 62. The letter requested information concerning the rate of release of propoxur from the collar, the method used to determine the active pet collar lifetimes, and the mode of action for a pet collar to “help EPA to refine the propoxur pet collar risk assessment.” In addition, the letter requested that Sergeant’s respond with ten days “on how your company intends to address these risk concerns”.

Importantly, the April 19, 2010, letter to Sergeant’s DID NOT refer to the current propoxur Docket 0806, DID NOT refer to the Scoping Document and PWP, DID NOT provide an opportunity for Sergeant’s to review and comment on the 2010 ORE, and DID NOT indicate that the Agency had any pre-determined preferred mitigation, namely, “voluntary” stop shipments of the products. Rather, because the Agency requested certain information to assist in refining the risk assessment, specifically the rate of release information, Sergeant’s understood that the published PWP for Docket 0806 was still the anticipated schedule and that during the DCI process, the technical active ingredient registrants would be required to generate studies addressing the immunotoxicity and CCA data requirements and the end-product registrants would be required to generate product specific data.

Although Sergeant’s was not involved in discussions between the Agency and Wellmark which transpired between the end of April 2010 up to and including June 8, 2010, it is our understanding that telephone conferences with Monica Wait and others in PRD were increasingly difficult and that by the call on June 2nd, the Agency had indicated that they were considering undertaking action to prohibit the sales of the Pet Collars past the end of 2010. However, examination of Ms. Wait’s follow-up conference notes for these calls indicates something quite different:

“We are continuing to evaluate some of the suggested refinements in Wellmark’s May 3, 2010 letter and will get back to you soon regarding those points.”

¹¹ NRDC Comments, page 3

¹² NRDC Comments, page 4

¹³ Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars, DP Barcode D371250, April 7, 2010.

"EPA confirmed that this information [Wellmark laboratory data regarding the release of propoxur from collars] could be useful in refining the pet collar risk assessment."

"A CCA study could be used to refine the FQPA factor and could potentially lower EPA's level of concern to less than 1,000 [in response to Wellmark indicating that they may conduct the CCA study]."¹⁴

"[Wellmark should] Provide information on propoxur pet collar production cycles, shipping and sales timing, and suggestions for interim mitigation measures."¹⁵

Sergeant's participated in a conference call with Wellmark and the Agency on June 9, 2010, in which Ms. Wait summarized the current status of the Agency schedule for resolving the Propoxur Pet Collar risk assessment issues, additional data that HED is recommending in order to refine the ORE, propoxur registration review actions, and interim mitigation measures. We were informed of the following:

- PRD management has decided that the single chemical reviews must be completed by December 2010 to facilitate the NMC cumulative review. This means that the data requested to be conducted to refine the risk assessment must be submitted to the Agency by some unknown date before the end of December 2010.
- IRB is recommending (not a DCI requirement under the Registration Review) generation of data under 2 studies: CCA and Pet Fur Residue Transfer. Both studies require review and approval of the study protocols by the Agency prior to initiating the studies. In the course of this discussion, it was agreed that Sergeant's and Wellmark (the "End Product Registrants" or "Registrants") would prepare a schedule based on discussions with laboratories for the conduct of those studies, which the Agency would review and thereby determine the protocol review period.
- The Agency intends to post the 2010 ORE to both Docket 0806 and the NRDC petition docket in the form it was provided at the same time as the Agency posts the Final Work Plan. We were not provided with a precise target date for posting, but were assured that posting to the docket was imminent.
- The Agency wants to implement some type of interim mitigation measure as a demonstration of their response to the margins of error ("MOEs") calculated in the 2010 ORE. Ms. Wait said that the Agency considers temporary suspension of sales as an appropriate interim mitigation measure. Ms. Wait stated clearly, however, that interim mitigation measures are "voluntary measures on registrants' part; the Agency does not intend to proceed under imminent hazard provisions." Ms. Wait said that the Agency is requesting the End Product Registrants' input on alternative interim measures.

This conference call was followed by Ms. Wait's email of June 17, 2010, to the End Product Registrants which requested submission of "your proposed timeline for submission of the CCA and pet fur residue transfer study protocols, reports, and other interim steps to meet

¹⁴ Email of May 18, 2010 from Monica Wait to James McFadden

¹⁵ Email of June 3, 2010, from Monica Wait to James McFadden

the 12/10 deadline by close of business on June 23rd." This email confirmed that the Agency intends to post the 2010 ORE with the FWP and that the Agency does not intend to revise the 2010 ORE prior to posting on the dockets. And, finally, this email states the Agency is "envisioning mitigation measures that would limit the availability of the product while studies are being conducted. Label amendments would not accomplish this goal."

In summary, the Agency's apparent need to respond to the NRDC petition appears to have contaminated the published Registration Review schedule. The Registrants have been provided with contradictory and piecemeal information concerning steps in the Review process, including expensive studies more appropriately conducted by the technical active registrants rather than the End Product Registrants and studies (pet fur residue transfer) which have never previously been conducted. And finally, the Registrants are being implicitly strong-armed into a "voluntary" shipment cessation without regard for the long-term consequences of such actions.

Flaws in the Agency's Revised Procedure for Conducting the Propoxur Registration Review

In summary, Sergeant's understands that the Agency is considering taking the following steps regarding Propoxur Pet Collars:

1. Imminently posting the 2010 ORE to the public docket for Docket 0806
2. Requiring the End Product Registrants to conduct a CCA study which benefits all propoxur risk assessments, not just pet collars, without the issuance of a Data Call-In Notice.
3. Requiring the End Product Registrants to conduct a Pet Fur Residue Transfer study, without the issuance of a Data Call-In Notice.
4. Requiring the End Product Registrants to conduct and submit data under the studies described above by December 2010
5. Requiring the End Product Registrants to implement interim mitigation measures which limit the availability of the products while the studies are being conducted.¹⁶

The Agency's regulations at 40 CFR Part 155, Subpart C set out the procedures which the Agency must follow in conducting the registration review program required under FIFRA §3(g). The steps described above are inconsistent with both the intent and the requirements of these regulations. Specifically:

1. *Imminently posting the 2010 ORE to the public docket for Docket 0806.*

The regulations at 40 CFR §155.52(b) provide that "In the course of a meeting with a person outside of government, the Agency or that person may provide the other with a copy of a document or other written material that has not yet been released to the public. The Agency will place a copy of any such document or other written material in the docket along with the minutes of the meeting where the materials were exchanged."

¹⁶ Notwithstanding this description, the Registrants anticipate that the Stop Sale Mitigation Measures will actually include, at least, time for the Agency to review the data and conduct a new assessment.

Subsection 155.52(b) provides that the "Agency will place minutes of such meetings in the docket when it takes action under §155.58. *At its discretion, the Agency may place minutes of such meetings in the docket sooner.*" (emphasis added)¹⁷ Sergeant's urges the Agency to adhere to the regulations and place the 2010 ORE in the Docket 0806 at the time of the proposed registration review decision. Placing the 2010 ORE in the docket alone and out of context with additional data considerations will serve to mislead the public concerning the risk presented by the Propoxur Pet Collars and will immeasurably damage Sergeant's in the marketplace without basis. We urge the Agency to exercise its good judgment and allow the registration review process to unfold as it is intended under the regulations and avoid hasty publication of partial, misleading, and, we believe, erroneous, information which overstates the potential risk.

In addition, as discussed below under point 5, while Sergeant's does not believe that posting of the 2010 ORE is required under the regulations, if the Agency does decide to post to the docket, the regulations at 40 CFR §155.53(c) require that if the Agency prepares a draft risk assessment or a revised risk assessment, the assessment will be made available for public comment for a period of at least 30 days. We have been informed that the Agency does not intend to re-open the public comment period. The 2010 ORE was generated after the close of the public comment period. To post the 2010 ORE without providing for public comment effectively forecloses any opportunity for public review and comment. Such opportunity for public review and comment is a cornerstone of the entire review process and should not be omitted.

2. Requiring the End Product Registrants to conduct a CCA study which benefits all propoxur risk assessments, not just pet collars, without the issuance of a Data Call-In Notice.

and

3. Requiring the End Product Registrants to conduct a Pet Fur Residue Transfer study, without the issuance of a Data Call-In Notice.

The regulations at 40 CFR §155.53 control the conduct of a pesticide's registration review. Section 155.53(b)(2) provides that "If the Agency finds that additional review of an individual product's registration is needed, it will review... to determine whether the registration of the individual product meets the FIFRA standard for registration. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice...." Sergeant's submits that this is precisely the circumstance of propoxur and the Propoxur Pet Collars. If the Agency believes that new data must be generated, the Agency is required to issue Data Call-In notices.

4. Requiring the End Product Registrants to conduct and submit data under the studies described above by December 2010.

The Agency has identified data needed to adequately assess the risk; those "data gaps" are specified in the Scoping Document; the schedule for issuing the anticipated Data Call-In notices is set out in the PWP and, presumably, in the FWP. For the Agency to require of the End Product Registrants via telephone calls and emails an accelerated schedule for such studies is contrary to the Agency's own regulations. The Agency's

¹⁷ Section 155.58, of course, provides the procedures for the issuance of a proposed registration review decision.

proposed time table for generating Data Call-In notices, receiving the data generated, reviewing the data and issuing a Preliminary Risk Assessment is set out in the PWP; the comment period on such PWP has closed. For the Agency to dramatically revise the schedule without public review and comment is inconsistent with the entire intent of making the process available to the public.

5. Requiring the End Product Registrants to implement interim mitigation measures which limits the availability of the products while the studies are being conducted.

Section 155.53(c) provides that "The Agency will generally make available for public review and comment a draft risk assessment for a pesticide if a new risk assessment has been conducted. The Agency will publish a notice in the Federal Register announcing the availability of the draft risk assessment and provide a comment period of at least 30 calendar days. The Agency will publish a notice in the Federal Register announcing the availability of a revised risk assessment, an explanation of any changes to the proposed document, and its response to comments. If the revised risk assessment indicates risks of concern, the Agency may, in the notice announcing the availability of the revised risk assessment, provide a comment period of at least 30 calendar days for the public to submit suggestions for mitigating the risk identified in the revised risk assessment." There is no mechanism in the regulations or under the statute, absent the threat of imminent hazard, for the Agency to require a "temporary sales suspension".

Flaws in the April 7, 2010 ORE

Sergeant's has undertaken a technical reassessment ("Reassessment Report") of the child hand-to-mouth risk assessment using product specific rate of release data and incorporating recent Agency estimates of the transferable residue fractions. Such report will be prepared by Exponent, Inc. and will be provided to the Agency in hard copy and electronic form this week. Discussion of the results of the Reassessment Report provided below relies on preliminary data from the Reassessment Report; the Final Reassessment Report should be consulted prior to reliance on the specific values contained in this letter.

The 2010 ORE is fundamentally flawed. It uses an unreasonable rate of release assumption and does not make use of the Agency's recently proposed transferable residue factors. As a consequence, the resulting estimated MOEs indicate a risk which is out of proportion to the estimated risk which should result if the assessment is properly conducted. Further, anticipated data resulting from the CCA study should refine the level of concern for propoxur and transferable residue studies should refine the exposure estimates. The data currently available and potential revisions to the SOPs suggest that much higher MOEs, as compared to those calculated in the 2010 ORE, are likely.

The Reassessment Report will address the flawed calculations as follows:

(1) Rate of Release: Sergeant's, by appendices to the Reassessment Report, will provide chemical-specific data from historical on-animal studies¹⁸ concerning the rate of release

¹⁸ The appendices to the Reassessment Report are intended to provide information which should be used to evaluate the flaws in the 2010 ORE and assess whether the 2010 ORE accurately represents a correct assessment calculation. Sergeant's is aware that the data are not of the type which would support a registration application; these data are historical.

of propoxur from pet collars. These data indicate that up to 18% of the propoxur initially present in pet collars may be released over the first 15 days following application, which is in sharp contrast to the Agency assumption in the 2010 ORE that 100% of the propoxur was released from collars in that time frame¹⁹. Such assumption of a 100% release in 15 days is unreasonable. Whereas the Agency estimated in the 2010 ORE MOEs of 28 for cat collars and 62 for dog collars registered by Sergeant's, incorporating *only* the rate of release data into the hand-to-mouth exposure estimates for children results in estimated MOEs of 380 for the cat collar and 364 to 466 for the dog collars.

(2) Transferable Residue Factors: Sergeant's believes that a further refinement to the exposure estimates, beyond the use of specific rate of release data, is appropriate based on recent Agency transferable residue factors. The current Agency default assumption is that 20% of the active substance on a pet is available as transferable residue. However, a review of transferable residue data (91 data points from five studies) presented by EPA to the Science Advisory Panel as part of the proposed revisions to the standard operating procedures (SOPs) for residential exposure assessment²⁰ indicates transferable residue fractions ranging from 0.06% to 3.1%. **When the maximum value of 3.1% is used in place of the current default value of 20%, MOEs are estimated to increase to 2,450 for the cat collar and 2,350 to 3,000 for the dog collars.** Even in the absence of CCA data, these resulting risk estimates are above the LOC for propoxur of 1,000.

Lack of Agency Basis for Stop Sale Mitigation Measures

The Agency has neither the legal nor factual basis for requiring or insisting that the End Product Registrants limit the availability of the products during the data development period. Sergeant's submits that the Agency should not rely on nor make available to the public preliminary, very conservative, and, we believe, erroneous, risk calculations which are inconsistent with the real world results seen from decades of use of Propoxur Pet Collars. The Agency's June 11, 2009, Updated Review of Propoxur Incident Reports, which is included by reference in the April 19, 2010, letter to Sergeant's, states that

*"The evaluation of incident data for propoxur chemicals has reported (relatively low volume of incident, no moderate or severe health effects that are plausibly related to the pesticide in question, based on toxicological data, sporadic incidents of an undefined or non-specific nature such as that clear trends or patterns cannot be discerned) only 48²¹ number of incidents, symptoms appear generic and not confirmed to be related to exposure, there is no clear evidence of a trend or exposure pattern. **Therefore, at this time, there are no remarkable case reports which suggest a plausible association between a moderate or severe health outcome and exposure to pesticide propoxur nor can we discern any suggestion of a trend or pattern regarding the health effects***

¹⁹ This assumption by the Agency that 100% of the propoxur was released from the collars in the first 15 days was not apparent from the 2010 ORE, but was provided in verbal explanation to James McFadden with Wellmark. The Agency's explanation is consistent with their resulting calculations.

²⁰ US Environmental Protection Agency. 2009. "Draft Technical Guidelines: Standard Operating Procedures for Residential Pesticide Exposure Assessment." Present to the FIFRA Scientific Advisory Panel for the meeting on October 6-9, 2009. 568 pages.

²¹ It should be noted that there were only 48 total incidents over an 8 year period and only 8 of those incidents related to collars.

due to the alleged exposure to pesticide propoxur. The current review of the incident data does not warrant further investigations at this time.” (emphasis added)

To the best of our knowledge, there is no “temporary sales suspension” provision in the statute or regulations for products that are lawfully registered and in compliance. If imposed by the Agency, such temporary sales suspension would be the equivalent of either a cancellation or suspension of the products. FIFRA requires that a cancellation must be based on either noncompliance or a determination that the product poses a risk of unreasonable adverse effects.²² The data required to be submitted under FIFRA §6(a)(2) are specifically designed to provide the Agency with information regarding such adverse effects. And such effects are noticeably absent.²³ In addition, the statute requires that a suspension may only be ordered, short of extraordinary emergency circumstances, in conjunction with a cancellation order and that the suspension must be accompanied by findings based on the prevention of an imminent hazard during the time required for cancellation proceedings²⁴.

Both cancellation and suspension orders provide for clear notice to the registrant and the opportunity to request a hearing. The statutory and regulatory provisions regarding cancellation and/or suspension have clearly not been met. In the event notice is provided to Sergeant's of the Agency's intent to initiate proceedings under either the cancellation or suspension provisions of FIFRA, Sergeant's will avail itself of its rights to a hearing.

Commercial Effect of Stop Sale Mitigation Measures and Inability to Accomplish Agency Goal

As described above, Sergeant's has been informed that the Agency desires that the End Product Registrants engage in a voluntary suspension of sales of the products while the data are being developed²⁵. We understand that the Agency's underlying assumption regarding the stated timeline for this Stop Sale Mitigation Measure is that data can be developed before the end of 2010, thus limiting the availability of the Propoxur Pet Collars for approximately the last six months of 2010. Even if the data were able to be developed within this time frame, limiting consumer access to these products cannot occur without serious and permanent market disruption. The vast majority of Propoxur Pet Collars are distributed to end users via retail sale. The realities of retail distribution are that product which appears on the retail shelves during the summer and fall/winter of 2010 were likely purchased by the distributors some six or more months prior. In order to effect a voluntary Stop Sale, some notice, at a minimum, to the distribution chain would need to occur. ***Any such notice, regardless of reason, will result in massive return of the product by the distributors at the expense of the End Product Registrants.*** The retail distributors will not keep product in inventory which may not be immediately sold; inventory space and retail shelf space are valuable and will not be allocated for product which for any reason cannot be sold. Such returned product is unlikely to be able to

²² FIFRA §6(b)

²³ In addition, for public health pesticides, the Agency is obligated to weigh the risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the product. FIFRA §2(bb)

²⁴ FIFRA §6(c)

²⁵ The Registrants believe that the more likely outcome is that the Agency will want the product unavailable during the entire period of data development, data submission and review, and Agency decision-making.

be reshipped for a variety of shelf life and damage in transit reasons. In addition, once a manufacturer loses "shelf space", it can be difficult and lengthy to recover that market visibility. Thus a voluntary Stop Sale is, in reality, a voluntary Recall, resulting in permanent significant damage to the marketability of the products.

Alternatively, the Agency appears to be considering achieving the goal of limiting the availability of product by effecting a voluntary suspension of either distribution of the product into the distribution chain or production of the product while the studies are being undertaken. We understand that the Agency is considering these options based on the repeated inquiries concerning production cycles and shipping/sales timing²⁶. The effect and timing of such measures will not achieve the Agency's stated goal and would result in significant market disruption and End Product unavailability. As described above, pet collars which are shipped to distributors this summer and fall tend to be in fulfillment of orders for retail sale during the winter and spring/summer of 2011. Thus, restricting shipments during the last six months of 2010 effectively restricts the availability of the pet collars during the spring and summer of 2011, by which time we anticipate that the study results would be available. A "suspension" or "delay" in production is additionally problematic since the complexities of pet collar production often necessitate a single, once a year production cycle. The production process is lengthy and often takes place during the winter months. Delay in production effectively damages product availability for the entire following year.

Alternative Mitigation Measures Proposed by Sergeant's

The sole risk upon which the Agency is basing their request for a voluntary Stop Sale Mitigation Measure is the residential post-application incidental oral (hand-to-mouth) exposure for children and toddlers²⁷. The Agency's preferred mitigation measure of limiting the products' availability implies a risk more general than the specific young child/toddler hand-to-mouth accidental ingestion risk. The End Product Registrants have discussed with the Agency an alternative mitigation measure of adding precautionary language to the product labels which addresses this risk. Out of hand, without reviewing any specific language proposal, the Agency has rejected such alternative mitigation strategy.²⁸

Sergeant's is requesting that the Agency reconsider this position. Further, Sergeant's is requesting that the Agency consider the addition of the following statement to the Precautionary Statements paragraph on the product packaging as a reasonable mitigation measure:

"To avoid accidental ingestion by young children,
wash hands after contact with collared animals."

Sergeant's believes that such language accurately and specifically targets the risk which is of concern to the Agency. Label precautionary statements are a recognized and effective risk mitigation measure. While we do not agree that the risk is accurately represented in the 2010 ORE, Sergeant's is willing to implement interim mitigation measures by the addition of supplemental precautionary language to the label. We request the Agency's assistance in determining the best mechanism to accomplish this label change. The Agency should understand, as described above, that any label change made to product produced this fall or

²⁶ See Monica Wait 6/17/2010 email.

²⁷ EPA letter to Sergeant's, April 19, 2010

²⁸ Monica Wait email of 6/17/2010

winter will be in the market place for a minimum of one year after implementing the change. Thus, without regard to the ultimate risk assessment, when calculated using CCA and Pet Fur Residue Transfer data, mitigation measures will have been implemented and the child ingestion risk further reduced.

Agency Request for Study Regarding Pet Fur Residue Transfer

The Agency has requested that the End Product Registrants conduct a Pet Fur Residue Transfer study which would determine the amount of pesticide on the pet's fur which is transferred to the hand. This study must be conducted under a protocol which is pre-approved by the Agency. This study would be the first study undertaken under the Draft Guidance Document for Developing Protocols Designed to Collect Pet Fur Transferable Residues Using Mannequin Hands. The Agency has requested that this study be completed and data submitted to the Agency by the end of 2010, although a specific date has not been communicated. Notwithstanding Sergeant's position that such data request must be initiated under a Data Call-In procedure, Sergeant's would agree to share in the cost of conducting such study. Further, Sergeant's would agree to make its best reasonable efforts to accomplish the goal of completing the study and submitting the results by the end of 2010. Toward that end, Sergeant's intends to attempt to meet the Agency's request for submission of an anticipated study schedule by the close of business on June 23, 2010, by participation in the schedule development by Wellmark. However, if the Agency takes steps which significantly impact the marketability of the product, Sergeant's may not be able to justify the costs of such data development.

Agency Request to End Product Registrants for Technical Active Study Regarding Comparative Cholinesterase Assay Study

As indicated in the Scoping Document, the Agency has identified "data gaps" for the technical active regarding immunotoxicity and CCA studies. The results from such studies will refine and contribute to the risk assessment for all products containing propoxur. Typically, such technical active data needs are met via a Data Call-In issued to the registrants for the technical active ingredient. The Agency in the current circumstance has, however, stated that the End Product Registrants must undertake the CCA study and must complete such study by the end of 2010. This is an unreasonable request. The data which would be generated during a CCA study cannot be completed by December 2010 under any circumstance. In addition, the data which would be generated under this study would benefit all registrants of products containing propoxur; there is no justification for the Agency to require the registrants of the Propoxur Pet Collars to bear the burden²⁹ of developing these data. However, notwithstanding Sergeant's position that such data request must be initiated under a Data Call-In procedure, and that such Data Call-In is more appropriately issued to the technical active registrants, Sergeant's would agree to share in the cost of conducting the CCA study. Further, Sergeant's would agree to make its best reasonable efforts to accomplish the goal of completing the study and submitting the results as expeditiously as possible. Toward that end, Sergeant's intends to attempt to meet the Agency's request for submission of an anticipated study schedule by the close of business on June 23, 2010. However, if the Agency takes steps which significantly impact the marketability of the product, Sergeant's may not be able to justify the costs of such data development.

²⁹ Notwithstanding the potential return of some of the costs through the data compensation provisions of FIFRA

In summary, the End Product Registrants are concerned that the Agency is intending to take precipitous action regarding the publication of an inherently flawed risk assessment document which unfairly and erroneously communicates a risk estimate which is based on an unreasonable assumption regarding the rate of release. Nor is that estimate consistent with the real world experience of consumer use of the Propoxur Pet Collars for decades. The End Product Registrants are seriously concerned that the Agency is intent on achieving an interim mitigation measure which would effectively destroy the market for the End Products, while alternative interim mitigation measures could address the specific risk of concern to the Agency. By this letter, the End Product Registrants have requested a meeting with appropriate Agency staff to discuss these matters. And the End Product Registrants have specifically requested that such meeting take place prior to the Agency making the 2010 ORE available to the public.

Please note that this letter was prepared for and on behalf of Sergeant's Pet Care Products, Inc. By signature below, Wellmark International has indicated agreement with the statements in this letter and consented to inclusion in the meeting request.

Thank you for your consideration of these issues. We look forward to additional discussion at your earliest convenience.

Sincerely,



Deborah A. Chadbourne
Attorney for Sergeant's Pet Care Products, Inc.

cc: Monica Wait, Chemical Review Manager, PRD
Robert Scharf, President, Sergeant's Pet Care Products, Inc.
Kelly Hoskins, Manager of Technical Affairs, Sergeant's Pet Care Products, Inc.
James McFadden, Sr. Regulatory Project Manager, Wellmark International, Central Life Sciences
Steven R. Spaulding, Senior Director, Regulatory Affairs, Central Life Sciences, Wellmark International

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By signature below, Wellmark International, concurs with the statements and conclusions provided above, concludes that the statements and conclusions are applicable to the Wellmark registrations 2724-454, 2724-275, 2724-491, and 2725-493, and requests that the Agency agree to participate in a meeting regarding the issues described with Sergeant's and Wellmark personnel as soon as possible.

Name: Steven R. Spaulding
Title: Senior Director, Regulatory Affairs

6/22/10
Date