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OMB Proposed Bulletin for Good Guidance Practices - 2005- 20
January 13, 2006

Comments of the Consumer Specialty Products Association (CSPA)

Regarding

OMB Proposed Bulletin for Good Guidance Practices

2005 -20

January 13, 2006

Executive Office of the President
Office of Management and Budget
Washington, DC 20503
E-mail: ljones@omb.eop.gov

Subj.: **Consumer Specialty Products Association**
Comments on Office of Management and Budget Proposed
Bulletin for Good Guidance Practices - 2005-20

Dear Sir or Madam:

The Consumer Specialty Products Association (CSPA) is a national nonprofit trade association representing over 260 companies engaged in the manufacture, formulation, distribution and sale of specialty products for consumer and institutional use. Our member companies produce a wide range of products such as disinfectants, disinfectant cleaners, household insecticides, insect repellants, and rodenticides. These products provide important public health benefits to consumers and are vital in protecting against disease and infestation.

CSPA supports OMB's proposed bulletin and we appreciate OMB's recognition of problems associated with OMB's implementation of "Guidelines." We believe that certain modifications could be made in the draft bulletin which would substantially improve it. CSPA's experience in the use of guidelines comes, in particular, from the Pesticide and Antimicrobial Divisions of the Office of Pesticide Programs (OPP). In addition, CSPA has an Antimicrobial Division that would be severely affected by any kind of mandatory labeling compliance. Our comments are divided into two major areas, the first concerning general comments and the second part addressing very specific provisions.

GENERAL COMMENTS

The Need for Good Guidance Practices

CSPA is in support of OMB's efforts to clarify the purposes of guidance documents and to impose procedures for issuance of such guidance for all agencies. We believe that this document is "quite a step" in the right direction. However, there is still much to be done with respect to the proper use by agencies of guidance documents.

CSPA's Members are very diverse and are competing against each other in the market place. In fairness to all concerned, each of these firms need consistency in regulatory requirements as well as in agency guidance documents. We believe that this draft

document could provide much stability in the area of the issuance of guidance by Federal agencies. With respect to CSPA, the comments herein are addressing the Environmental Protection Agency's Guidance Documents issued by the Office of Pesticide Programs.

History of PR Notices

For many years, the Office of Pesticide Programs (OPP) used Pesticide Registration Notices (PR Notices) with the intent to compel compliance with these documents by the pesticide registrants. These notices go back many years, and were used to circumvent the due process of Notice and Comment Procedures of the Administrative Procedures Act (551 USC). PR Notices were originally called Pesticide Regulatory Notices. Almost every time CSPA visited EPA, the first agenda item for discussion would be that the Agency was using the PR Notices as though they were regulations which had undergone through a proper regulatory process. That, however, was not often the case. Time after time we told the Agency it was violating the notice and comment procedures of the Administrative Procedure Act.

Subsequently, as a result of CSPA's continuous argument, EPA changed the name of the PR Notice from Pesticide Regulation Notice to Pesticide Registration Notice. This was done to move away from the appearance that PR Notices were regulations of mandatory compliance with regulatory requirements set forth in the PR Notices. While progress with EPA's use of PR Notices has been made, there are still problems with respect to the EPA issuance of PR Notice Guidance documents. In 2003 CSPA visited the Director of the EPA Office of Pesticide Programs (OPP), Marcia Mulkey, and explained our great concern with the use by EPA of these PR Notices to implement them as regulations or mandatory changes in pesticide labeling. In a letter to this writer dated April 3, 2001, Ms. Mulkey addressed the arguments which we made at that meeting. The letter acknowledged that there were problems with the use of the PR Notices. See April 13, 2001 letter from Ms. Marcia Mulkey Exhibit I herein.

We acknowledge that the problem of misuse of guidance documents by EPA has improved, but there still are considerable issues which need to be addressed. For instance, EPA's multiple approval of proposed and final regulations by many persons is very slow and painstaking. With at least a three year wait for approval of the final regulation, there is surely a tendency for EPA OPP Staff to try to accomplish the task at hand by the use of "guidance" documents. Moreover, we believe that the guidance documents need to be read and understood by EPA's Staff in order to recognize the importance of guidelines as compared to regulations and the role of guidance by use of PR Notices.

There have been cases in the past where guidance language was properly used in the body of a PR Notice only to have mandatory language elsewhere in the document regarding pesticide label changes or compliance requirements with other "Guidance.". An illustration of this appears in a 2001 PR Notice entitled "Final Guidance for Pesticide Registrants on Pesticide Resistant Management Labeling." After several references to guidelines for labeling, the document states:

> "…. For the matters covered by this particular PR Notice, EPA also does not expect to require that any registrant adopt the labeling set forth here as part of any individual licensing decision or action. However, if any registrant seeks to use the language set forth here in the manner and circumstances described here, EPA does generally expect to find such language acceptable in any licensing proceeding."

See Exhibit 2 listing PR Notices which are intended by EPA to be mandatory to registrants.

EPA's Use of Letters to Require Unauthorized Label Changes

In a couple of instances, EPA, OPP Staff tried to impose labeling changes on registrants of metered insecticides by virtue of a letter sent to a number of such registrants but not to all of them. It was the Agency's opinion that certain label changes were necessary and thus, registrants were the subject of an attempt to require mandated language without adherence to notice and comment requirements. Attached as Exhibit 3 is a letter from EPA advising some registrants of metered insecticides of necessary and mandatory label changes.

This method of obtaining compliance with labeling changes by a simple letter is perplexing. In this particular case, the product was a metered insecticide product which is utilized particularly in southern cities or overseas and which discharges at certain intervals. The purpose of such product is to knock down and kill flies, mosquitoes, and other insects which threaten the public health and which are present in great numbers in those particular geographical areas. Based on extremely bad and duplicative alleged incidences of illness, EPA Staff by letter attempted to obtain compliance with the following label change: "This product is not for use during business hours." The effect of this labeling requirement would mean the end of such a product. The purpose for this product is to keep the facility "charged" so that the product will be highly effective. Thus, the Agency tried to impose labeling requirements which were not appropriate without proceeding through rule making. See Exhibit 4, October 19, 2004 CSPA's letter to Lois Rossi discussing Procedural/Legal Issues, Pages 1 & 2.

Why EPA Does Not Like to Use the Rule Making Process?

One thing which becomes evident is that the Agency, for a variety of reasons, would prefer not to utilize the rule making process except for the most urgent areas. This is because the internal EPA review process takes a long time until implementation of a final rule. We believe that much of the problem of EPA is the fact that it takes so long internally for each review to be signed off by the necessary Agency personnel.

Even when the Agency (EPA) obligates itself to rulemaking, there is a very long time before a rule is proposed, let alone promulgated as a regulation. For instance, the Agency's part 158 Data Requirements has not been modified for over twenty years. During this time, the Agency merely directed applicants to provide data by using criteria

which had never gone through rulemaking. Only recently EPA issued proposed data requirements and it may be several years before a final regulation is issued. In the meantime, the regulated community has very difficult time in making reasoned business decisions.

This problem is incentive not to have rule making but to work to require labeling changes by other actions without going through a long regulatory process. Obviously, if the Agency could force changes in labeling without going to rule making, this process could be substantially shortened. Based on the above factors CSPA requests that OMB extend the Bulletin and its prohibitions to letters and memorandums which do not presently adhere to guidance parameters set forth in the Bulletin.

Multi Labeling Activities – Guidance for Label Review

There are a number of label review efforts ongoing within the Agency. First, EPA reconstructed its label review unit so that registrants could get answers to labeling questions quickly. Secondly, the Pesticide Programs Policy Committee (PPDC) has appointed a committee to take a look at consumer labels and to make suggestions for their improvement. Third, several years ago, the Agency formed the Consumer Labeling Initiative (CLI) and this group funded investigations and developed data with respect to the understanding of consumers with respect to labels on products they purchase.

On the basis of all these factors, it appears to us, that EPA should reinforce the fact that adoption of suggested label changes would be clearly voluntary on the part of the registrants.

The Label Review Manual

Several years ago, EPA embarked on a mission to put forward a Label Review Manual (LRM) which was to contain all of the memorandums, PR Notices and other notices with respect to labeling of pesticides. From a stand point of continuity, this Manual does help immensely in providing guidance for labeling. The problem is, however that the Manual is often in conflict with the label regulations set forth at 40 CFR 156.10 and this causes a problem. EPA staffers in approving labels for registrants have often utilized the (LRM) and instructed the applicant to label his/her products according to it. In some case the (LRM) is not correct while in others the regulations are not correct. That does not mean that this document, which is undergoing its third examination by the Agency and registrant, should be eliminated. It contains important, documents, in one place. Often users of the (LRM) are under the impression that the use of the IT is required. To remedy this, a note should be contained in the preamble of the (LRM)l that states the use of the (LRM) is voluntary and is not required. It is particularly important that a guidance document be issued regarding this (LRM) and that readers of it are made aware that everything in the (LRM) is voluntary except for some regulations.

Review of Label Regulations

The Agency has not revised the labeling requirements set forth in 40 CFR 156.10 for a number of years. The last proposed revision of this regulation took place in approximately 1987 when EPA proposed revisions to labeling regulations. We don't know if CSPA's comments were taken into account because the proposal was never promulgated. The failure of the Agency to promulgate up to-date regulations is frustrating to the EPA Staff and pesticide applicants and further is a reason why the Agency attempts to fold guidelines into regulatory labeling requirements.

"Significant Guidance Documents" and Economically Sufficient Guidance Documents

It appears that there are only two prerequisites that would trigger an agency's obligation to comply with the Good Guidance Practices. These are that the Guidance is either of "significant guidance" or "economically significant guidance."

We are concerned that some of the guidance documents issued by Federal Agencies may not qualify for inclusion under the Good Guidance Practices thereby creating a void in the application of these practices. It is necessary that any guidance which does not meet the criteria of significant guidance documents or economically significant guidance documents should nevertheless be subject to its protective provisions. For instance, under the definition of a significant guidance document, such a document may not lead to an annual effect of $100 million or adversely effect, in a material way, the economy or a sector of the economy. In such case the criteria would not be met and the safeguards of the good guidance practices would not apply. Thus, an Agency which is treating a guidance document as rule may not be reachable for protection under the good guidance practices.

We believe that the provisions of the good guidance practice bulletin should apply in all cases where an Agency forgoes the requirements of the Administrative Procedures Act.

SPECIFIC COMMENTS

Page 9, I.d.3 (iii) Set forth initial interpretations or statutory or regulatory requirements or current interpretation or policy not made available to the public through the public comment process or charges in interpretation or policy – This suggested change would broaden the term "significant guidance document" to include a current interpretation or policy not made available to the public through the public comment process.

Page 9 II.a. - add the words and sign off after the words supervisory concurrence. This language would add the duty to have the Agency provide a signature of approval to the other requirements for departure from significant GUIDANCE documents.

Page 10 II.1.d. – Add a new paragraph – paragraph (d) (internet access) which requires that draft significant guidance documents will not be followed or implemented until

approved by appropriate senior agency officials, finalized and made available to the public.

II.2.(i) stronger language is needed to make it clear that guidance documents are voluntary and not mandatory regulations. Stronger language is also needed because many states view guidance documents as regulations and try to enforce them. Suggested language would be as follows:

> Each significant guidance document shall: include the term voluntary guidance (not a regulation which mandates compliance).

In the event that differences between an agency a registrant develop as to whether or not an agency is in compliance with the provisions of the Good Guidance Practices Bulletin, a third party from OMB should be designated to determine if the parties can agree whether or not these has been in compliance with the Bulletin.

II. C.2. Preamble - We agree with the description of "standard elements" in section II C. 2. of the preamble. We often see words such as "shall" and "must" in PR Notices, so we are pleased to see that this GGP document will address that point. PR Notices often state the "non-binding nature" of the Notice, but the "shall" and "must" statements are also present, along with a compliance date being presented at the end of the Notice. We concur with the explanation that public comments could be addressed by the issuance of another draft of the guidance document, with another expressed comment period. A guidance document should be clear and should not contain conflicting or confusing language.

Good guidance practices (GGP) should embody all of the criteria provided in the preamble of the document. GGP should provide for both agency and public review before the document is released to the regulated community and to the agency itself. The regulated community should be involved and consulted from the beginning of the guidance document development process. The regulated industry can often see effects that the agency cannot foresee. Working together results in a better guidance document. It is sometimes infrequent that the OPP involves the regulated industry to be involved in the discussions about a proposed Notice. Consultation with the regulated industry through trade associations or companies should be an early step in the process of developing any guidance document.

I. 1.2 & 1.3 on the Proposed GGP definition in item I., definitions in 2. and 3. should explicitly state that a guidance document will NOT be used by an agency to avoid the rulemaking process. A review of OPP's PR Notices will demonstrate that the agency has often used the PR Notice to sidestep the full rulemaking process. Bypassing rulemaking can also exclude a full discussion of the need and criteria for the Notice and public comment is also blocked by use of a Notice. Reviewing OPP often files on PR Notices will show that trade association letters will almost always note that the first objection to the Notice is based upon its being seen as a means to avoid formal rulemaking.. Many notices issued have been under discussion for many years and certainly did not require immediate use of a PR Notice.

We agree that an agency should have written procedures and criteria for writing and approval of a policy interpretation. An agency should not circumvent the "significant guidance document" approval process to achieve some other purpose. Similarly, the agency should not use the process to avoid rulemaking.

II..2. We concur with the expressed "standard elements" of the guidance document, especially item (vii) concerning the use of mandatory language. We find that the EPA/OPP consistently ends its PR Notices with a statement of "non-enforceability" but then it goes on to provide "shall" statements with implementation deadlines. This is not acceptable if the intent of the Notice is truly to provide non-binding guidance.

Conclusion

Thank you for allowing us to make comments on this proposed Bulletin For Good Guidance Practices.

Sincerely,

Stephen S. Kellner
Senior Vice President & General Counsel

EXHIBIT 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 3 2001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Steve Kellner
Consumer Specialty Product Association
1913 Eye Street, NW
Washington, DC 20006

Dear Mr. Kellner,

I am glad we had the opportunity to meet on February 21, 2001, and discuss your concerns surrounding the EPA Office of Pesticide Programs' (OPP) use of Pesticide Registration (PR) notices. I believe our exchange during the meeting helped clarify our rationale for using PR notices in the way we do and helped us better understand your concerns. I am pleased that you agreed that PR Notices are useful mechanisms to convey some Agency notifications and interpretive guidance. As I indicated, the program has historically used PR notices for many years to articulate Agency interpretation of existing rule language. As noted in my earlier letter of November 1, 2000, to Doug Nelson of the American Crop Protection Association, the program has historically used PR notices for several purposes, including providing 1) information about program activities (e.g; 2000-7, Non-Dietary Exposure Task Force), 2) statements of policy and procedure having future effect (e.g; 1999-1, Import of Unregistered Pesticides Intended for Export) and 3) interpretations of statutory and regulatory requirements concerning pesticide labeling (e.g; 2001-1, First Aid Statements on Pesticide Product Labels). It is this last that was of particular concern to you and your associates at the meeting.

During the meeting, I agreed to provide you with a written summary of the commitments that I made on behalf of OPP with regard to our continued use of PR notices. The commitments I made to you are as follows:

> Notice and Comment - OPP will provide adequate time for all interested parties to comment on draft PR notices and will refrain from issuing labeling language PR notices which are deemed to be effective upon issuance, but which ambiguously provide for a comment period. In a very few instances, though, it may be appropriate to issue some PR notices for certain topics that are immediately effective without providing a comment period. We would expect these to involve very simple and non-controversial matters.

Response to Comments - OPP will prepare a response to comments document for each PR notice for which comment is requested and make the response to comments available in the public docket. This will help enable commenters to know how their comments were considered in revising the draft PR notice.

Clarity - OPP will strive to make future PR notices clearer as to whether the labeling guidance pertains to purely voluntary matters or pertains to Agency interpretations that may become mandatory through pesticide licensing actions. When the opportunity for addition of labeling language is purely voluntary or suggestive in nature, we will not use "effective dates" for the addition of such language to the label.

Consistency of Interpretation - OPP will work to better ensure that our intent in each PR notice is clear and understandable to states and OPP staff to reduce the possibility of differing interpretations of the notice.

Applicability of PR Notice Guidance - As OPP reviews individual applications for registration and amendments for registrations, we will consider individual rationales from registrants who believe that a PR notice is not applicable to their specific product. If the Agency agrees with the rationale, documentation will be provided to the registrant that the interpretation or approach set forth in the PR notice is not being applied in that specific case and the reason(s).

I also committed to include in this letter a statement of where and how we believe persons can challenge the application of any interpretations set forth in PR notices. A PR notice is an interpretative document, that binds neither the Agency nor the regulated community. As such, registrants and applicants may ask the Agency to change its interpretation and the Agency is free to change or deviate from its interpretation if there is a reasonable basis for doing so. If the Agency uses an interpretation announced in a PR notice in the context of a regulatory decision, the regulated entity can challenge both the substance of the interpretation and its applicability to the decision at hand in an appropriate forum. The "appropriate forum" varies depending on the type of decision involved. In the first instance, almost all regulatory decisions begin as informal staff level decisions which can be challenged within the informal setting of discussions and correspondence between the Agency and the regulated entity. If the Agency seeks to implement its decision by means of cancellation, suspension, denial of registration or amendment or a refusal to act, the regulated entity will have legal recourse either in formal adjudicatory hearings or in federal court. In any such proceeding, the substance and applicability of any interpretation that has been announced only in a PR notices will be open to challenge by the regulated entity.

In response to a request at our meeting, you should have received by now via email, a listing of PR notices that have been issued by the Office of Pesticide Programs. Also, as promised during the meeting, we have provided Dr. Has Shah of the American Chemistry Council our response to comments document that was prepared and placed in our public docket on January 10, 2001, for PR Notice 2001-3, First Aid Statements.

OPP is committed to working with stakeholders in an open and constructive way. If you have questions or concerns about any of our PR notices, I hope that we can continue to discuss them in a productive manner. Please don't hesitate to contact my office at 703-305-7090 if you have any questions.

Sincerely,

Marcia E. Mulkey, Director
Office of Pesticide Programs

cc: Brigid Klein, Consumer Specialty Product Association
Ray McAllister, American Crop Protection Association
Gabriel Eckstein, American Crop Protection Association
Allen James, American Crop Protection Association
Julie Spagnoli, Bayer Corporation

EXHIBIT 2

Please note that the full text of many of the PR Notices or other pertinent documents are listed in total in EPA's website at http://www.epa.gov/PR_Notices/

Some pertinent PR Notices are:

1. Draft PR Notice 2000-XX - Regarding: Bee Label Statements, in particular stating that the label changes must be completed by October 1, 2002 and the if a product does not meet the requirement of §40 CFR 156.10, the Agency may find the product to be misbranded. (See also CSPA comments on this PR Notice below)

2. Draft PR Notice 2000-5 of May 10, 2000 which sets forth guidance for mandatory and advisory labeling statements.

3. PR Notice 2000-3 of May 1, 2000 – First Aid Statement on Pesticide Product Label. Updating First-Aid language which, states that registrants re not required to revise labels to respond to the Notice "at this time." However, EPA advises that registrants should begin to revise the label immediately and EPA "expects that registrants of existing products" will begin to revise their labels accordingly. It is the Agency's goal that all product labels be revised by October 1, 2001.

4. Draft PR Notice 2000-XX – Pertaining to Indoor Residential Insecticide Product Label Statement. Advising that a PR Notice itself does not impose binding obligation on pesticide registrants or EPA. EPA requests that all products subject to this Notice sold after October 1, 2002, bear labeling consistent with this notice. In the event that EPA identifies a risk concern identified with any indoor residential insecticide, these dates could change and/or additional regulatory measures may become necessary.

Via Email: opp.docket@epa.gov

January 22, 2001

Public Information and Records Integrity Branch Information Resources and Services Division Office of Pesticide Programs
Environmental Protection Agency
Room 119, CM #2
1921 Jefferson Davis Highway
Arlington, VA

RE: Docket Control Number OPP-00684, Draft PR Notice 2000-XX, Bee Precautionary Labeling Statements

Dear Sir/Madam:

These comments are submitted on behalf of the Consumer Specialty Products Association (CSPA), formerly known as CSMA, regarding the draft PR Notice 2000-XX, Bee Precautionary Labeling Statements, see 65 FR 70350. CSPA is an association representing more than 220 companies. Several of our members are engaged in the manufacture, formulation, distribution and sale of non- agricultural pesticide and antimicrobial products that are registered pesticides under FIFRA, and thus regulated by EPA.

As noted to EPA on numerous occasions, CSPA objects to the use of PR Notices to convey mandatory label changes to registrants. PR Notices are guidance documents intended to provide general information of a non-regulatory nature. Therefore, mandatory label and compliance requirements must be promulgated through notice-and-comment rulemaking, pursuant to the Administrative Procedure Act, as amendments to EPA's Part 156 labeling regulations, not issued in the form of PR notices.

There are numerous examples of changes being made by the Draft PR Notice that are only appropriate to be done under rulemaking as follows:

The Draft states that there is continued controversy over the adequacy of the labeling statement currently found at 40 CFR 156.1 0(h)(2)(ii)(E), which means that the regulation itself should be reexamined, not that changes should be made through a PR Notice.

The input that the Agency sought from SFIREG, AAPCO and the State Labeling Issues Panel on the labeling text should all be part of a rulemaking record.

The draft PR Notice proposes to exceed the scope of the authority of the Agency by extending the bee precautionary language beyond the use patterns described in 40 CFR 156.1 0(h)(2)(ii)(E).

The Draft PR Notice states that the products "should bear the following statement..." and gives specific language that is to appear on the label. Thus, EPA is attempting to make mandatory label changes through a guidance document.

. The Draft PR Notice acknowledges that the new policy "may effectively prohibit the use of certain pesticides on blooming crops." Such an action therefore will result in a significant regulatory change without notice and comment rulemaking.

. Regarding the potential impact in the clearly defined use areas described in the cited regulation (that of agricultural crop, forestry and shade tree, and mosquito abatement) proposal of the notice as a regulation would allow important observations to be expressed. For example, in the area of mosquito abatement, it is possible that an application could drift into an area containing plants that are "blooming, pollen-shedding, or nectar producing" without the applicator being aware of such drift. Agricultural and non-agricultural areas are often the site of mosquito adulticide application, where the applicator may not be aware of the presence of plants that are "blooming, pollen shedding, or nectar producing. In a proper rulemaking proceeding, these and other factors could be discussed in comments and would be included in a public record of the proceedings.

. EPA states that any notification to the Agency of the label changes not consistent with the terms of the notice may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA. Thus, the Agency clearly intends to use the PR Notice to enforce its provisions in violation of the APA rulemaking requirements.

EPA is improperly utilizing the PR Notice mechanism to impose label requirements and compliance dates and obligations on registrants without proceeding under the required notice and comment rulemaking procedures. CSPA urges the Agency to rescind the draft PR Notice and proceed instead through notice and comment rulemaking. Thank you for the opportunity to comment on this matter.

Sincerely,

Stephen S. Kellner Senior Vice President Legal Affairs

EXHIBIT 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Dear Registrant:

Subject: Label Modifications to be Requested for Metered Insecticide Spray Products

The Agency is eager to increase the safe use of pesticides. EP A and several state health departments collaborated with the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health and the National Center for Environmental Health to investigate incidences of acute pesticide-related illnesses associated with automatic pesticide dispensers. This findings were published in a short report, "Illnesses Associated With Use of Automatic Insecticide Dispenser Units - Selected States and United States, 1986-1999" published in the Morbidity and Mortality Weekly Report on June 9,2000 (pp. 492-495). The report described cases, summarized the surveillance data and provided recommendations for safe dispenser use.

From 1986 through 1999, 43 known cases of acute pesticide illnesses associated with automatic pesticide dispensers were reported. Thirty-five incidents involved persons exposed while at work, including seven incidents that occurred during the replacement of dispenser cartridges or attempts to service faulty dispensers. Seven cases were the result of persons exposed while they were customers in restaurants and one case involved a movie theater customer.

Resmethrin, a pyrethroid insecticide, was implicated in three cases. The active ingredients in the remaining 40 cases were pyrethrin/piperonyl butoxide/N-Octyl Bicycloheptene Dicarboximide. Most insecticide dispenser related illnesses occurred when dispensers were improperly placed too close to food handling, dining or work areas; were placed where ventilation currents carried the mist to such areas; and/or were serviced by persons unfamiliar with proper maintenance of these units.

.For these reasons, the Agency believes that the labeling for all automatic metered insecticide dispenser units must be amended to include the following statements. Attachment A lists products subject to these requested label changes.

1. Do not use in nurseries or rooms where infants, the ill or aged persons are confined. (Required since these products are labeled for use in hospitals.)

2. Do not install directly above or within 12 feet of any food handling or food dispensing area. Metering devices must be timed not to dispense while food processing is underway. Foods must be removed or covered during treatment. All food processing surfaces must be covered during treatment or thoroughly washed with an effective cleaning compound followed by a potable water rinse before using.

3. Do not install within 3 feet of air ducts.

4. Do not use in public places while customers or workers are present. Timers must be set to dispense only during non business hours,

5. Carefully follow directions for the dispenser unit when installing the dispenser and replacing cans or conducting maintenance.

Due to the continued reports of incidents involving exposure of humans to insecticides as a result of the use of these products, the Agency believes that these statements must appear on all labels for these products.

We request your full cooperation to make the changes listed above immediately. Please submit the draft labeling which incorporates these changes for review within 30 days of this letter. If these changes are not made voluntarily and incidents continue, the Agency may pursue further regulatory action.

As you may know, the process of reregistration for the active ingredients in these types of products has begun. During reregistration, chemicals registered prior to November 1, 1984 are reassessed to ensure that they meet all current standards, including those of the Food Qualify Protection Act (FQP A) of 1996. As a result of the risk assessment perforned during the reregistration process, further labeling changes and or regulatory action may occur.

If the list included as Attachment A does not represent all of your products affected by this letter, please identify that produc1(s) with your response. If you have any questions. please call Joseph Tavano of my staff at (703) 305-6411.

Sincerely,

Arnold E. Layne

EXHIBIT 4

October 19, 2004

Ms. Lois Rossi
Director of Registration Division
US EPA, Office of Pesticide Programs
Crystal Mall 2 Room 713C
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Labeling of Metered Insecticides

Dear Ms. Rossi:

As a follow up to our meeting on July 13, 2004, we thought it would be a helpful to review some of our concerns and provide further information to EPA regarding the use of Metered Insecticide Sprays. This is particularly important since we understand that the agency is presently asking registrants to incorporate label language which was the subject of our meeting, and which we found objectionable. In addition, the last section of this document provides information concerning the risk assessment which will be conducted.

This letter, therefore, will address (1) procedural/legal issues, (2) the history of Metered Insecticide Aerosol Products, (3) the number of alleged incidents used to justify revised labeling, (4) composition of metered insecticide products, (5) dermal route of exposure, (6) inhalation route of exposure, (7) placement of device, and (8) conclusion.

1. Procedural/Legal Issues

At our meeting, we stated our concern for the manner in which EPA is attempting to mandate label changes for certain registered products. Specifically, EPA sent letters to some marketers of metered aerosol insecticide products mandating certain label changes. While we are always willing to meet with the Agency to discuss labeling issues, we must again advise EPA that the way these labeling requirements were issued does not meet the procedural safeguards required by the Administrative Procedure Act since there was no notice and opportunity

to comment prior to issuance of the letters. EPA, therefore, must discontinue this practice.

There are significant problems for registrants when the Agency attempts to require label changes for a class of products without input from the regulated community. For instance, only some of the registrants of Metered Insecticide Products received letters while others did not know of EPA's actions. This creates a double standard because some registrants might make the label changes while others may choose not to relabel or others may not know of the EPA position regarding label changes. Thus, the labeling could be different for products that are vertically identical and registrants, therefore, are not able to conduct business on a level playing field.

When labels of a class of pesticide products are to be changed by EPA letters to individual companies, the registrants are deprived of the opportunity to work with the Agency to explain why the changes might be improper or to suggest other language to revise labels. In the instant case, EPA, among other required label changes, sought to require label instructions that users of metered insecticides were not to have the products functioning during hours where customers might be present. This directive presents major problems for registrants because the labeling requirements are not only unwarranted, but if implemented will result in the loss of this valuable product form because use of the product is prohibited during regular business hours. As noted below metered products are not effective unless they are used all the time.

As you may recall, we obtained a letter from Marsha Mulkey which concludes that PR notices are, in most cases, guidance, and not regulatory requirements (*Attachment 1*). The practice of issuing letters to direct label changes is more egregious than issuance of a PR notice and clearly, if PR notices are guidance, then letters like the one in question here, are improper and are "below PR notice status" and therefore, unenforceable.

Those registrants that received the letter were instructed to make the label change or face possible enforcement action. Not only is this type of regulation procedurally deficient, but it is also impractical and unfair to registrants. The Agency should wait until the reregistration process for the product is completed and then, if warranted, with proper notice and comment procedures, make the changes at the same time for every registrant in that product class.

Registrants need stability if they are to continue manufacturing metered insecticide products which have significant public health benefits. For

instance, registrants and users need to know that the product may be used in places where food is served. EPA should also base its label

requirements upon risk assessments to determine whether or not there is a problem with placement of metered insecticide products or whether or not there are exposure issues.

EPA should also have appropriate supporting data or validated reasons for proposing labeling changes and such information should be open for scrutiny and should be scientifically appropriate, and properly reasoned.

2. History of Metered Insecticide Aerosol Products

Automatic metered dispensers have been in use for over 50 years. The first generation of these products were cumbersome units that had to be plugged into an AC outlet, and operated only in the places where electric outlets were available. Even with limited applications, the products proved so successful that new innovative battery operated dispensers have been developed. These are portable devices that are easy to install and operate. It is estimated that several million of these devices are in use world wide providing protection against disease carrying insects.

One of our members has been selling these metered products in Canada and other countries without a single known documented case where an individual's health was affected, either due to misuse or the correct use of the product. Metered aerosols were developed to be used in a "Timed Aerosol Dispenser". Not only does a metered insecticide use Pyrethrin, which is approved for use in food areas, but it is also dispensed in much smaller quantities than are released by hand held products, fogging equipment or other liquid applications. The principle used in the manufacture of these products is "minimum dosage for "maximum effect".

A hand held spray pesticide product normally sprays about 10 grams of product per 10 seconds of actuation, thus 350 grams of the product will have only 35 applications. A metered aerosol containing 180 grams will generally last 30 days. A six gram product is "puffed" using a time release aerosol dispenser, and provides 24 hours of protection for approximately 30 days. The product is highly effective in controlling insects.

Another very important factor is that Pyrethrin is not only an effective killer of dangerous insects, but is an excellent insect repellent. The acceptance of the automated dispenser by users shows that these devices are highly effective and are trusted for their efficiency, safety record, and ease of use. Efficacy of this type of product can be seen by

users and if the product's performance was in doubt, use of the products would be abandoned.

The aerosol products and dispensing systems are sold to many developing countries, where sanitation is poor. These countries regard mosquitoes and flies to be a major health risk to their citizens and to visitors and have climates where flies, mosquitoes and other insects pose very serious health concerns. These countries are benefiting from a very

effective low cost protection system by using metered aerosols and dispensers to control insects which are vectors for dengue fever, malaria, yellow fever, Lyme disease, West Nile virus, Chagas disease, encephalitis, and other diseases.

3. Number of Alleged Incidents Used to Justify Revised Labeling

Although EPA based its action on incidences of possible exposure of the pesticide, the cited cases were duplicative and few in number (approximately 43 in 10 years). EPA, in this case, apparently made its decision to require label changes, in part, based on two complaints from a person who was allegedly sprayed twice by an automatic devise dispensing the product.

This, of course, raises the question why that person chose a restaurant with a metered device after he allegedly was already sprayed once. Based on discussions at the July 13th meeting, apparently EPA in part based its new label requirements on these two "complaints" – clearly not a number that should ordinarily invoke a response by a Federal Agency involving considerable staff and resources and problematic in preserving administrative due process requirements.

In developing countries, insects are vectors of many diseases. The feed back from many end users from various countries has been significant. These users state that these products, when in operation, reduce the insect population in their surroundings and reduce the risk of being infected by the bites from mosquitoes and other blood sucking vectors of diseases. Doctors and nurses have recommended the use of metered insecticide devices to protect people from pesky insects and preserve public health. After 30 days, when the aerosol can is emptied, the users can see the increase in the insect population in their surroundings and they move quickly to replace the canister.

We continue to believe that the number of incidents reported in the CDC Morbidity and Mortality Report are extremely small relative to the number of units that are produced and used each year. We have

previously suggested that EPA look at the production data that is annually reported to the Agency in order to get a clearer picture of how the reported number of 43 incidents from 1986 through 1999 relate to the number of units manufactured. We believe that certain of the incidents which reportedly occurred while the aerosol can was being installed in the unit have already been addressed by the newly developed actuator with a built in delay feature. We would like EPA's feed back addressing whether the Agency has concluded that there is a trend of increasing or decreasing incidents. We would like to see an explanation of the Agency's findings in this regard if they are available. Additionally, we would like to know if EPA has confirmed the 43 incidents reported by the CDC with data from 6(a)(2) reports to EPA?

We note that fragrance aerosols or air fresheners are also used in these time metered devices. We also would like to know if the reports of incidents of seeing or smelling the discharge were confirmed to be incidents of insecticide use and if the cans of product were removed and verified to be an insecticide product and if so, whether there is documentation of these findings.

From the data that we have seen, there did not appear to be any cases of serious effects from the alleged exposure, even in the case of the person who was allegedly "sprayed in the face" on two occasions. The insecticides used are not highly toxic or irritating. The dose applied is also quite small.

4. Composition of Insecticide Products

The metered aerosol category of products typically consists of two preferred products, with the first being 1.80% Pyrethrins and 10.0% Piperonyl Butoxide (PBO) while the other product contains 0.974% Pyrethrins, 1.950% PBO, and 3.210% MGK 264. Both of these products are registered for use in food processing plants, hospitals, homes, stores, hotels, motels, schools, and other public buildings as well as dairies, barns, milk houses, canneries, breweries, and food handling establishments.

For all of the products, the directions are essentially the same. Metered dose aerosol devices and the can of product are designed to be activated every 7.5 minutes, deliver a dose of 27.5 milligrams of product every 15

minutes and deliver a dose of 55 milligrams of product into the air. The most common activation time is every 15 minutes. The device is designed to treat 6,000 cubic feet of air space. Given the fill of the aerosol can, the unit will operate for about 30 days and will then require a new

can of product to be installed. The units are typically battery operated so that placement is not dependent upon an electrical outlet being nearby.

5. Dermal Route of Exposure

Given the activation frequency of the device and the fixed dose expelled by the mechanism, there will be 55 milligrams of product discharged into 6,000 cubic feet of air space every 15 minutes or, for the product containing the highest level of Pyrethrins and PBO (1.80% Pyrethrins and 10.00% PBO), the unit is discharging 0.99 milligrams (or 990 micrograms) of Pyrethrins and 5.5 milligrams (5500 micrograms) of PBO into 6,000 cubic feet of air space. Assuming an 8 foot ceiling height, the floor surface area would be approximately 750 square feet. So if we assume that all of the active ingredients ultimately fall onto horizontal surfaces, we would have each dose of 55 milligrams of product delivering 1.32 micrograms of Pyrethrins and 7.33 micrograms of PBO to each square foot of horizontal surface. This assumes an equal distribution of product over the 750 square feet of horizontal surface and rules out any distribution on walls or other surfaces.

We can change the room dimensions and look at a 10 foot ceiling and a 600 square foot floor surface area and the numbers will change slightly. We would theoretically have the same 55 milligrams of product distributed evenly over 600 square feet or 1.65 micrograms of Pyrethrins and 9.16 micrograms of PBO for each square foot of horizontal surface. This also rules out any distribution of residues on walls or other surfaces. This deposition of PY and PBO residues is far below any LD50 levels or NOEL levels for the dermal route of exposure. Further evaluation of the transfer of Pyrethrins and PBO residues to human skin must consider the fact that the transferability of residues from hard surfaces to human skin is very low (<2%) and that the dermal penetration and absorption of PY and PBO is also very low (<2%). The dermal hazard, therefore, would appear to be very low.

Thus, if we assume that the Pyrethrins and PBO equally distribute over the horizontal surfaces such as floors, tables, working surfaces, etc., we would anticipate that the degradation of the actives and the physical removal of deposited residues by wiping of tables and work surfaces would prevent the accumulation of significant residues of the actives. In

facilities such as food handling establishments and restaurants, patrons do not generally stay for long enough periods of time to be present for more than 3 or 4 discharges of 55 milligrams of product in a 6,000 cubic foot area. There is hardly time for a buildup of residues during that time.

Floors are mopped at least daily and the tables are wiped with disinfectant cleaner after each use.

A report from the University of Illinois, College of Agriculture from 1970 reported that the half-life of Pyrethrins was 7 hours, while PBO had a half-life of 72 hours and MGK had a half-life of 4 hours. The study was conducted with an "intermittent Pyrethrin Dispenser" which discharged 100 milligrams, twice the amount used now, into 6,000 cubic feet of space. The report states that "only 1% of the aerosol emission is recoverable from a surface." The report states that in a test over 21 days of continuous exposure, residues in exposed foods showed "insignificant levels of Pyrethrin and synergists". The short half-life reported in this study demonstrates that surface residues from intermittent aerosols are not persistent. This report was part of the large volume of data supplied to Ms. Debbie Edwards after our meeting with her on this matter.

6. Inhalation Route of Exposure

If we look at the inhalation route of exposure and consider the 8 hour exposure for a worker in a facility where a metered aerosol device is installed and operating and look at the 90 day rat inhalation toxicity NOAEL for Pyrethrins, it is 11 milligrams per cubic meter of air. The metered aerosol unit discharges a dose of 0.99 milligrams (990 micrograms) of Pyrethrins per activation into 6000 cubic feet of air. This converts to 169.9 cubic meters, which means that there are 5.826957 micrograms per cubic meter or 0.0058269 milligrams of Pyrethrins per cubic meter of air, or more than an order of magnitude less than the inhalation NOAEL every 15 minutes.

Because of particle size and the fact that particles fall over time, by the time that the next discharge occurs, there are no airborne Pyrethrins as particulate material. Furthermore, given typical air exchanges in a

facility, the opening and closing of doors in an establishment, the fluid dynamics of air in a room, and the degradation of Pyrethrins and PBO by sunlight and other factors, there is little possibility for Pyrethrins and PBO to remain airborne for significant periods of time to become a hazard. The dose is also more than an order of magnitude less than the NOAEL for PY.

In a 1970 report prepared by CAP, Inc. of Orange, California, particle size and fallout of particles is discussed. The intermittent aerosol is designed to produce particles less than 50 microns, with 80% less than 30 microns. According to the report, 20 micron particles have a hang time of five (5) minutes in still air. Particles of 30 microns have a three (3)

minute hang time and 50 micron particles have a one (1) minute hang time. Clearly the "puff" of product discharged is small and the hang time for particles is of short duration, further contributing to the low probability of inhaling a sufficient quantity of active ingredients to cause an acute toxicity response or a chronic toxicity response. This report was supplied to Ms. Debbie Edwards after our first meeting, along with a considerable amount of other data used to support the intermittent aerosol products.

For the product which contains 0.974% Pyrethrins, 1.950% PBO, and 3.210% MGK 264, the same 55 milligrams of product is discharged by the device each 15 minutes or 27.5 milligrams of product per 7.5 minutes. The amount of Pyrethrins discharged each time is 0.5357 milligrams in 6,000 cubic feet of space. The amount of PBO is 1.0725 milligrams and the amount of MGK 264 discharged is 1.7655 milligrams per 6,000 cubic feet of space. Obviously this is far less Pyrethrins and far less total active ingredients discharged. We have not presented discharge and deposition calculations for that reason.

7. Placement of Device

Certainly proper placement of the unit is essential to proper operation and desired insect control. Placement instructions for the device are printed on the carton or in the instructions in the carton. Placement and mounting instructions, along with the instructions for installing the aerosol can of insecticide or odor control product should be on or with the device, not on or with each aerosol unit of insecticide. New actuator devices are designed with a built in delay so that when the aerosol can is replaced, there is a 10 second delay before the first discharge of product. This is a safety feature that is designed to prevent an accidental discharge of the new unit when the person is close to the unit.

We feel confident that the manufacturers of actuator devices will be happy to modify the directions of the device to comply with the Agency's request with regard to not placing the unit near an air return intake.

8. Conclusion

We reaffirm our position that intermittent aerosol products are protective of public health by controlling flies and other pests that vector pathogenic organisms and contaminate food products. The intermittent aerosol is the solution to a pest problem, not the cause of health problems. There are very large numbers of these units in operation and the number of incidents reported regarding them is extremely small, given the number of annual applications of products. The proposed label

revision to prohibit use of intermittent aerosol products while customers are present is not supported by any of the data sited by EPA. Moreover, the single complaint of an individual claiming to have "been sprayed in the face" on two occasions should not be used to justify unnecessary labeling requirements or removal from the market place of these public health pesticides. Intermittent aerosol devices have been shown to be ineffective in controlling pest populations when employed "after hours only". The products need to be operational around the clock.

We appreciate the opportunity to meet with you and to forward you information which we feel is very important to the continued availability of metered insecticide products. We wish to advise that McLaughlin Gormley King is sponsoring a risk assessment study based on the incidents described in information sent to CSPA in response to a Freedom of Information Request – HQ-RIN-1778-02. The study is to be conducted by Science Strategies L.L.C. If you have any questions, please call me at 202-833-7307. For your information, I am sending two copies of our booklet entitled, "Dangerous Pests – The Impact of Insects on Human Health" *(Attachment 2).* This booklet presents pertinent information regarding house flies, mosquitoes and other insects which EPA should consider before advocating changing labels of metered insecticide products. You may also wish to visit our website "aboutbugs.com".

Sincerely,

Stephen S. Kellner
Senior Vice President & General Counsel

cc: Marion J. Johnson