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MEMORANDUM

Via E-Mail

DATE: December 28, 2007

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Updates Lists of Inert Ingredients and Extends Comment Period on Draft PR Notice

Today's *Federal Register* includes notices from the U.S. Environmental Protection Agency (EPA) announcing updates to the lists of inert ingredients permitted in pesticide products applied to non-food sites and an extension to the deadline for comments on the draft Pesticide Registration (PR) Notice entitled "Label Statements Regarding Third-Party Endorsements & Cause Marketing Claims." Comments on the draft PR Notice are due **March 27, 2008**. EPA last updated its lists of inert ingredients in 2004. Each notice is discussed in more detail below.

Lists of Inert Ingredients

The Office of Pesticide Programs (OPP) website now includes the following updated lists of inert ingredients permitted in pesticide products applied to non-food sites, including those permitted for use in minimum risk pesticides exempted under Section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and those eligible for the U.S. Department of Agriculture's (USDA) National Organic Program:

- **Non-Food Inert Ingredients** -- These inert ingredients are permitted for use in pesticide products applied to non-food use sites, such as ornamental plants, highway right-of-ways, rodent control, etc. The list is available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.
- **Food-Use Inert Ingredients** -- The only inert ingredients approved for use in pesticide products applied to food are those that have either tolerances or tolerance exemptions. According to EPA, the electronic Code of Federal Regulations, available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl, has



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the most up-to-date tolerances and tolerance exemptions. EPA states: "Please note that many food-use inert ingredients have use limitations and restrictions."

- **Minimal Risk FIFRA Section 25(b) Inert Ingredients** -- These inert ingredients are approved for use in minimal risk pesticide products under FIFRA Section 25(b); they are called "4A" inert ingredients. The list of inert ingredients is available on the Internet at http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf.
- **USDA's National Organic Program Inert Ingredients List** -- The National Organic Program inert ingredients list is available at <http://www.ams.usda.gov/nop/NoticesPolicies/NOP5008ReassessedInertIngredients09-06-07.pdf>. A brief overview of EPA's role in the National Organic Program is available at on the Internet at http://www.epa.gov/opprd001/inerts/epa_nop.pdf.

On the OPP website, EPA states that the List Category policy "has now served its purpose as a tool for prioritizing the evaluation of chemicals." Now that EPA has completed reassessment of food tolerances and tolerance exemptions under the Food Quality Protection Act (FQPA), there are no longer inerts classified as List 1, 2, or 3. According to EPA, all food-use inert ingredient tolerances and tolerance exemptions "are considered to be safe when used according to the conditions set forth in the CFR's text and tables." EPA is still using the "4A" category for the purposes of FIFRA Section 25(b), and USDA is still using "List 4" for the National Organic Program. EPA states: "For non-food inert ingredients, the 1987 List Category policy remains pertinent (including labeling) for those identified as 'List 1' (toxicological concern)." EPA's old inert lists are available at <http://www.epa.gov/opprd001/inerts/oldlists.html>.

Draft PR Notice

On October 31, 2007, EPA announced the availability of the draft PR Notice regarding "Label Statements Regarding Third-Party Endorsements & Cause Marketing Claims." Today's notice extends the comment period until **March 27, 2008**. The draft PR Notice is available on the Internet at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=090000648033376b&disposition=attachment&contentType=pdf>.



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The draft PR Notice describes EPA's framework for evaluating proposed statements and graphic material to appear on pesticide labeling regarding third-party endorsements or a relationship between the pesticide registrant and a charity ("cause marketing claims"). The draft PR Notice identifies factors EPA may consider in reviewing applications for registration or amended registration with labeling that contains either third-party endorsements or cause marketing claims. The draft PR Notice also identifies the types of discussion and information that applicants could provide to support EPA review of such applications, including mock labels, documentation of the third-party endorsement or information to substantiate the truthfulness of the cause marketing claim, and a discussion of potential consumer impacts, including consumer market research when appropriate. EPA states that, in some cases, it could approve a proposed label statement but conditionally require the registrant to provide additional information to assess whether adverse consequences resulted from the addition of the label statement.

EPA's October 31, 2007, *Federal Register* notice announcing the availability of the draft PR Notice requested comment on the following questions:

1. Are there other standards in FIFRA, besides the misbranding standards at Section 2(q) and the unreasonable adverse effects standards in Sections 3(c)(5) and 3(c)(7), that EPA should use in deciding whether to approve third-party endorsements or cause marketing claims?
2. Under what circumstances could the use of a label statement containing a third-party endorsement or cause marketing claim affect a consumer's assumptions about efficacy or safety?
3. EPA is seeking to ensure that its decisions whether to approve third-party endorsements or cause marketing claims have a sound basis. Please suggest how EPA might judge whether to request additional information to assess the impacts of a claim on consumers.
4. Please comment on what additional types of information EPA should request to assess the impacts of a claim on consumers' assumptions about efficacy or safety or about whether a claim detracts from other information presented on the label.
5. What, if any, restrictions should there be on the types of organizations that can participate in third-party endorsement or cause marketing claims on labels?



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6. What, if any, restrictions should there be on the types of symbols that can be used on labels, to minimize the potential impact of consumers' assumptions about efficacy or safety?
7. How should EPA evaluate whether label statements containing a third-party endorsement or cause marketing claim detract from other information presented on the label?
8. How should EPA maximize the effectiveness of disclaimer language when it is used to mitigate the potential for misunderstandings?
9. Are there other factors EPA should consider when evaluating third-party endorsements or cause marketing claims on labels?
10. Please identify and explain why any particular population groups may be more vulnerable to adverse impacts or more likely to misunderstand label statements regarding third-party endorsements or cause marketing claims.
11. What kind of public participation process, if any, is appropriate when EPA evaluates a specific proposed label statement regarding a third-party endorsement or a cause marketing claim?
12. Should EPA consider imposing a time limitation with regard to approval and use of the third party endorsement label that is granted?
13. One proposal is that registrants could use a hang tag, wrap around, shrink wrap or other approach to display cause marketing language or a third-party endorsement. Please comment on this proposal.
14. Under what circumstances, if any, should the contents of an application to add a third-party endorsement or cause marketing claim to the label of a registered product be treated as Confidential Business Information (CBI)? What information should be required to support a claim of CBI?

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We hope this information is helpful. As always, please call if you have any questions.