DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

March 7, 2005

Nancy L. Buc
Kate C. Beardsley
Buc & Beardsley
919 Eighteenth Street, N.W.
Washington, D.C. 20006-5503

Dear Ms. Buc and Ms. Beardsley:

This letter responds to your October 22, 2004, request for reconsideration of complaint and request for correction pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, 114 Stat. 2763A-153 (2000) (the Federal Data Quality Act) concerning the Food and Drug Administration's (FDA's) Consumer Campaign on Safe Use of OTC Pain Products (the campaign). Your original complaint, dated May 18, 2004, and the October reconsideration were submitted on behalf of your client, McNeil Consumer and Specialty Products (McNeil).

FDA has carefully reviewed your request for reconsideration and finds no new information that would compel the agency to amend the campaign at this time. Because FDA already addressed many of your statements in the August 25, 2004, response, I will not repeat them here. Instead, I wish to address several of the broad statements you have made with regard to FDA's August response and the campaign. Before I do that, however, I would like you to know that the agency is considering some campaign modifications. Although some elements of the campaign are no longer amenable to change (e.g., the *FDA Consumer* article titled, "Use Caution With Pain Relievers," which appeared in the January-February 2003 issue), FDA may alter several ongoing elements, such as the print ads. The agency is also planning to make some format changes to the public service advertisement for non-steroidal anti-inflammatory drugs (NSAIDs) to highlight stomach bleeding and kidney problems if we use the advertisement in the future.

With regard to your October 22 request for reconsideration, you state that "FDA's response (dated August 25, 2004) does not dispute that the campaign as a whole creates the impression that acetaminophen is more dangerous than NSAIDs." In fact, the conclusion of our August 25 response explicitly states that "we do not believe that the campaign understates the risks of NSAIDs or implies that acetaminophen is more dangerous than NSAIDs." Your October 22 request also states that FDA's response to your complaint focused "primarily on individual examples of statements that contribute to the campaign's lack of objectivity." The mainstay of your complaint that the campaign exhibited bias was

your presentation of a cumulative collection of examples of statements made by FDA. In our response, we refuted each example to respond to your allegation regarding the collective effect of such statements.

Another statement in your October 22 request for reconsideration is that the campaign "as a whole, and certain elements of it, represent that acetaminophen is less safe than NSAIDs, as unequivocally demonstrated *by the press response* to the campaign" [emphasis added]. You have failed to provide any evidence to support your allegations regarding the nature of the press response. Moreover, the press coverage cannot be attributed to or controlled by FDA, and neither it nor your interpretation of it would constitute a substantive basis for our reconsidering the campaign's content.

After careful consideration of your request for reconsideration, we have concluded that the request does not provide a basis for further action regarding the campaign. In addition, we maintain that the education campaign, either as a whole or any of its parts, does not violate the Federal Data Quality Act standards for objectivity. In view of our decision, we do not feel that a meeting with McNeil concerning the campaign is warranted.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

Document Name: G:\Wp\BETHC\COMMISSIONER RESPONSE\McNeil Complaint Reconsideration.doc

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Cleared: CGanley, HFD-560, 12/13/04
Cleared: JBull, HFD-105, 12/14/04
Cleared: LLemley, HFD-006, 12/17/04
Cleared: JJenkins, OND, 12/17/04
Cleared: JAxelrad, HFD-005, 12/21/04
Cleared: SGalson, CDER, 12/22/04
Edit:BClarke:OES, 12/23/04
Edit:BClarke:OES, 12/28/04
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1/10/05 Bgreenberg (DHHS) question on footnotes
Edit: BClarke, OES, 1/11/05
Clear:WOsborne, OES, 1/11/05
Returned to Barbara Greenberg w/edits:1/11/05
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October 22, 2004

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Steven K. Galson, M.D., M.P.H.
Acting Director
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Food and Drug Administration
5515 Security Lane
Rockville, MD 20852

Re: Request for Reconsideration of Complaint and Request for Correction to Federal Data Quality Act Concerning "Consumer Campaign on Safe Use of OTC Pain Products"

Dear Drs. Crawford and Galson:

On May 18, 2004, Buc & Beardsley submitted to Dr. Crawford on behalf of McNeil Consumer & Specialty Products ("McNeil") a complaint and request for correction under the Federal Data Quality Act ("FDQA")[1] (the "Complaint"). The Complaint explained why the FDA "Consumer Campaign on Safe Use of OTC Pain Products" (the "Campaign") lacks objectivity as required by the FDQA, and requested a correction. The Complaint is attached at A. On August 25, 2004, FDA denied the request in the letter attached at B ("FDA Response").[2] McNeil hereby requests reconsideration of the Complaint for the reasons set forth below.[3]

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1. Section 515(a) of the Treasury and General Government Act for Fiscal Year 2001, Pub. L. No. 106-554 (Appendix C), 114 Stat. 2763A-153 (2000).

2. CDER authorized an extension of time until October 22, 2004 to submit this request for reconsideration.

3. This request for reconsideration is addressed to Dr. Galson as the signer of the FDA response to the Complaint and to Dr. Crawford as the official to whom the Complaint was addressed.

The Campaign As A Whole

The Complaint was divided into three sections. First, it established the representation created by the Campaign as a whole – that acetaminophen is more dangerous than NSAIDs.[4] Second, it demonstrated that the representation is not true – that acetaminophen is not more dangerous than NSAIDs.[5] Third, it explained that, because the representation is not true, the Campaign lacks objectivity, and thus is not in conformance with the FDQA.[6] FDA's response does not dispute that the Campaign as a whole creates the impression that acetaminophen is more dangerous than NSAIDs. The agency takes issue with some assertions about whether individual pieces represent that acetaminophen is less safe than NSAIDs,[7] but does not disagree that the Campaign as a whole created that impression. FDA would be hard put to do so, given the press coverage of the Campaign, which, as detailed in the Complaint, focused almost entirely on acetaminophen risk.[8]

FDA also does not dispute that it would be untrue to communicate that acetaminophen is more dangerous that NSAIDs. Indeed, it could not do so. Unless consumers overdose, acetaminophen is an extremely safe drug, having almost no side effects. Acetaminophen overdose, while serious, is very rare.[9] NSAIDs, especially aspirin, have the potential for serious adverse reactions even at the labeled OTC doses. Chronic repeated use of greater than OTC

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4. Complaint at 5.

5. Id. at 7.

6. In the FDA's response, the Agency seems to imply that McNeil's Complaint is an attempt to impose unnecessary administration burdens, to inhibit FDA from disseminating important information to the public, and to second-guess what information FDA determines is appropriate for dissemination to the public. FDA Response at 2. McNeil's only purpose was to point out the Campaign's lack of objectivity and to request its correction, permissible and desirable purposes of the FDQA's complaint process. Complaint at 2-4.

7. See FDA Response at 4.

8. See Complaint at 6. FDA's response does not even address the press coverage or its implications.

9. As discussed in the Complaint, McNeil is aware of the risks associated with acetaminophen overdose, has taken steps to communicate these risks to the public, and appreciates FDA's assistance in that regard. Attached at C is the storyboard for a recent Tylenol ad that has been running on network television as part of McNeil's effort to educate consumers to use acetaminophen only at recommended doses. In the ad, Brenda Bass, Vice President of Sales for Tylenol, tells consumers that she would rather lose sales than see consumers exceed recommended doses.

recommended doses of NSAIDs markedly increases the risk of GI and renal toxicity, particularly GI bleeding. NSAID complications are more common than acetaminophen complications.[10] For these reasons, among others, it is simply not true that acetaminophen is more dangerous than NSAIDs. Thus, FDA's response fails to address the two central points of the Complaint – that a representation has been made and that the representation is inaccurate.[11] This fact alone mandates that a reconsideration reach a different conclusion.

McNeil does not suggest that the information on acetaminophen should not be disseminated. It should. McNeil objects to the failure to include important information on NSAIDs and the lack of balance in the presentation, which create the inaccurate representation.[12]

An FDA Campaign that sends an inaccurate, incomplete, and biased message about OTC pain relievers is of more than academic interest; it could have serious public health consequences. Sending the public a message that acetaminophen is more dangerous than NSAIDs will encourage consumers to switch from acetaminophen to NSAIDs, a decision that will inevitably lead to more morbidity (e.g., GI bleeds, kidney damage) and greater mortality.[13] Independent of the FDQA, FDA should, as part of its public health mission, correct the misleading impression it is creating.

The requirement under the FDQA that information be objective is explained by OMB as meaning that information must be accurate, clear, complete and unbiased.[14] The Campaign fails

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10. See Complaint at 7-8.

11. It may be that FDA has misunderstood the gravamen of the Complaint. The response suggests that FDA believes that it is responding to two separate issues, lack of objectivity and untruthfulness. FDA Response at 2. In fact, the two are linked; a Campaign that is not accurate, not complete and/or not unbiased is not objective.

12. See Complaint at 4-10.

13. See Complaint at 7-8 for a discussion of adverse events related to NSAID use.

14. For a discussion of the FDQA and the relevant standard, see Complaint at 2-5. See also section 201(n) of the Food, Drug, and Cosmetic Act ("in determining whether [promotion] is misleading there shall be taken into account (among other things) not only representations made or suggested . . . but also the extent to which the [promotion] fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the [promotion] relates . . .").

under that standard.[15] Having chosen as the Campaign's topic the "Safe Use of OTC Pain Products," FDA is required to provide an objective, i.e., clear, accurate, complete and unbiased, view of the topic as a whole. This has not been done. The Campaign as a whole, and specific elements within it, are neither accurate nor complete, and they express all too clearly FDA's bias.

Rather than addressing the central issue, FDA offers three rationales for the Campaign.[16] FDA's first rationale is that the agency may choose what risks to focus on in a specific public education campaign, and the fact that some risks are not discussed does not constitute a violation of the FDQA.[17] It is surely true that, as a general matter, FDA may focus on certain risks in a public education campaign. It may not do so, however, if the result is a Campaign that is inaccurate, incomplete, or biased; FDA is required to provide an objective view of the topic as a whole.[18] That is what the FDQA mandates.

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15. In the Complaint, McNeil also noted that under the FDQA, information likely to be influential in affecting individual behavior deserves particular scrutiny. Complaint at 3-4. FDA's guidelines define influential information in part as information that results from agency actions that will adversely affect in a material way "competition" or "public health or safety." U.S. Department of Health and Human Services Guidelines for Ensuring the Quality of Information Disseminated to the Public, Part II.F., Section VII.A. The Campaign should therefore be evaluated under the high scrutiny category. Although the FDA Response does not address whether high scrutiny was accorded to the Campaign, FDA's implication that the Complaint does not address issues that "materially affect the quality of information," FDA Response at 4, suggests that it was not.

16. FDA's response points out that McNeil "conceded" that the FDA News Release, the Science Background, and Health Hints do not violate standards of objectivity. FDA Response at 3. McNeil made this concession, Complaint at 4, in an effort to be fair and balanced in its Complaint. Concessions on individual pieces of the Campaign, however, are irrelevant to whether the Campaign as a whole is objective, or whether other components of the Campaign are objective.

17. FDA Response at 3.

18. The title of the Campaign – Safe Use of OTC Pain Relievers – is misleading on another ground as well. FDA does address the safe use of acetaminophen by pointing out that it is important not to overdose. It fails entirely to address how NSAIDs may be safely used, an enterprise that would require, among other things, much greater attention to the populations who should not use NSAIDs and explaining warning signs of trouble. Communicating how to use acetaminophen safely is a fairly simple matter. Communicating how to use NSAIDs safely is a more complex message. If the Campaign were actually about "Safe Use of OTC Pain Relievers," one would have expected the NSAID discussion to take most of the available space.

Second, FDA argues that the information cannot be viewed in isolation, noting that, on other occasions, the agency has provided information on NSAIDs without commenting on acetaminophen.[19] This may be so, but it is irrelevant to this inquiry. The FDQA would be meaningless if the government were able to import past communications into current ones to justify them. A consumer reading any particular communication would have to acquire all prior communications related to the topic to obtain objective information. Moreover, FDA's review process, which is mandated by the FDQA, would also have to consider all prior communications related to the topic to determine whether the one under consideration was objective.[20] The FDQA clearly envisions that each communication should be objective. In this case, the Campaign was required to present an objective discussion of "Safe Use of OTC Pain Relievers," without reference to past documents on this or other topics.

Third, FDA argues that McNeil's suggestion that the Campaign is untruthful because "NSAIDs are more dangerous than acetaminophen" is incorrect.[21] FDA has turned the Complaint on its head. McNeil did not, and would not, make this argument. McNeil said that the representation created by the Campaign – that acetaminophen is more dangerous than NSAIDs – is untruthful. McNeil did not say that NSAIDs are more dangerous than acetaminophen.[22]

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19. FDA Response at 3.

20. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002).

21. FDA Response at 3.

22. In this section of its response, FDA downplays the risks associated with OTC doses of NSAIDs because "[m]uch of the morbidity and mortality associated with the use of NSAIDs is in the prescription or professional label setting . . . ." FDA Response at 3. It is surprising to see FDA dismiss the risks associated with OTC NSAID doses so lightly. FDA proposes to make a number of risks, including GI bleeds and renal complications, mandatory parts of the OTC label. See, e.g., Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use: Proposed Amendment of Tentative Final Monograph, and Related Labeling, 67 Fed. Reg. 54,139 (Aug. 21, 2002). And the Nonprescription Drugs Advisory Committee ("NDAC") recommended that the risk information be further strengthened. Nonprescription Drugs Advisory Committee Transcript (Sept. 20, 2002) ("NDAC Transcript") at 216-220. McNeil's survey of the literature on the risks of OTC NSAID doses, which was submitted to NDAC and attached to the Complaint at Exhibit I provided convincing evidence that these risks are real. While it may be convenient for FDA to downplay those risks to avoid having to confront them in analyzing McNeil's Complaint, FDA does both its past statements on these issues and the public health a disservice by doing so.

Thus, none of FDA's three reasons is either responsive to McNeil's Complaint or independently persuasive.

Specific Portions of the Campaign

In explaining how the representation that acetaminophen is less safe than NSAIDs was created, McNeil used a number of illustrations taken from the documents that make up the Campaign. Two documents – the advertisements and the FDA Consumer article – contribute heavily to the lack of objectivity. Three other documents also contain specific illustrations of the problem. In its response, FDA has addressed each of the five documents at issue, and attempted either to refute that they emphasize the risk of acetaminophen over NSAIDs or to show that the acetaminophen emphasis was proper. Each of these is addressed below.

(1) Public Service Advertisements

In the Complaint, McNeil parsed the two ads at issue – one titled "Why is it important to know that all these medicines contain acetaminophen?" and the other titled "The best way to take your over-the-counter pain reliever? Seriously" – and pointed out ways in which the ads highlighted the risks of acetaminophen over those of NSAIDs.[23] FDA's response focuses on the fact that one ad is about acetaminophen, the other is about NSAIDs, and that no explicit comparisons between the two are made.[24] FDA's response does not address the point that McNeil made. McNeil's point is that the ads' emphasis on acetaminophen risk, and lack of emphasis on NSAID risk, help create the impression that acetaminophen is more dangerous than NSAIDs. The fact that the comparison is not explicit makes it no less real.

Just one example taken from the Complaint illustrates the point.[25] The headline of the acetaminophen ad says that it is about acetaminophen and clearly signals that there is an issue with acetaminophen. The headline of the NSAID ad fails to mention NSAIDs. The subhead in the acetaminophen ad reads "Because too much can damage your liver."[26] The subhead for the NSAID ad reads "Know the active ingredient in your pain relievers. Read the labels."[27] The acetaminophen captions focus on acetaminophen and explicitly state the risk. The NSAID ad fails

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23. Copies of the acetaminophen ad and the NSAID ad are attached at D and E, respectively.

24. FDA Response at 4.

25. Complaint at 5.

26. Exhibit D.

27. Exhibit E.

to reach either NSAIDs or risk in the captions, addressing them only in the small print. On these facts alone, FDA's statement that the print ads will not lead a consumer to believe that acetaminophen is more dangerous than NSAIDs cannot be correct.

FDA's response also states that the issue of OTC NSAID overdose "is not a major area of concern . . . ."[28] This is puzzling. It is true that acute overdoses of acetaminophen are more likely to cause serious adverse events. But serious adverse events related to chronic overdoses of NSAIDs are more common and can be quite serious.[29] FDA's response admits as much when it says that "[m]uch of the morbidity and mortality associated with the use of NSAIDs is in the prescription or professional label setting, where NSAIDs are taken in higher doses and/or for longer periods of time . . . ."[30] Risks include gastrointestinal bleeding, as well as liver and kidney toxicity. In addition, chronic uses of aspirin doses just above the OTC maximums can lead to serious cases of salicylism, which can be life-threatening and fatal in adults, even after just a few days of overdose. Consumers who take more of an NSAID at one time or chronically than recommended in the OTC labeling are in fact taking an overdose. That an OTC overdose may be the same amount of drug as a physician might prescribe or is discussed in professional labeling does not change the fact that as to an OTC consumer it is an overdose to take more than is recommended for longer than is recommended in the OTC labeling. FDA's response assumes that consumers must be warned in the Campaign about acetaminophen overdose, even though related adverse events are very rare. Yet it assumes that it need not include a warning about overdose of OTC NSAIDs.

Finally, FDA's statement that McNeil addresses format and style, but not content, suggests that the point has been missed.[31] Format and style are large contributors to the lack of objectivity in these ads, as well as the failure to include sufficient content on NSAIDs. McNeil appreciates your offer to make format changes in the NSAID ad to highlight stomach bleeding and kidney problems. While that alone is not enough to cure the lack of objectivity, it is a useful beginning.

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28. FDA Response at 4.

29. Dr. Crawford addressed NSAID risk just two weeks ago in connection with the withdrawal of Vioxx from the market, saying "All of the NSAID drugs have risks when taken chronically, especially of gastrointestinal bleeding, but also liver and kidney toxicity." FDA News: FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product (September 30, 2004).

30. FDA Response at 3.

31. FDA Response at 4.

(2) The FDA Consumer Article

In the Complaint, McNeil objects to the inclusion of the FDA Consumer article in the Campaign for the same reasons that it objects to the ads – because its focus on acetaminophen risk and failure to focus on NSAID risk helps create the misleading impression that acetaminophen is less safe than NSAIDs.[32] FDA has offered several rationales for the article, none of which addresses the point.

FDA argues first that the FDA Consumer article was intended to inform consumers about the deliberations of the September 2002 Nonprescription Drugs Advisory Committee ("NDAC").[33] Its purpose, however, is irrelevant to its role in this campaign. The article's clear overemphasis on acetaminophen risk helps distort the whole Campaign. Second, even as a description of the NDAC meeting, the article is not objective. NDAC met for two days, one of which was devoted to acetaminophen risk, the other to NSAID risk. The article does not reflect that balance at all, with seven specific paragraphs on acetaminophen risk followed by three general paragraphs on NSAID risk. And it surely does not reflect the sense of committee members who saw NSAID risk as more than equal to acetaminophen risk.[34]

Second, FDA explains that the article provided a balanced discussion of acetaminophen risk and benefit.[35] This is true; McNeil has not objected to the way in which acetaminophen risk was portrayed. FDA then says that more paragraphs were devoted to acetaminophen risk because more explanation was necessary to describe the situation.[36] Actually, acetaminophen risk is far easier to describe than NSAID risk because acetaminophen risk is related to overdose, whereas NSAID risk is related to use both under labeled conditions and at higher and longer doses. The FDA Response then seems to link the need for more discussion with people's failure "to use acetaminophen correctly, leading to significant liver toxicity, suggests that consumers do not understand the consequences of ingesting too much acetaminophen."[37] In fact, the liver toxicity associated with acetaminophen overdose is extremely rare and, when it occurs, is often

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32. Complaint at 5-6.

33. FDA Response at 5-6.

34. At the NDAC meeting, Dr. Katz explained that "GI bleeds and deaths from GI bleeds in this country are a big problem. They are a much bigger problem than the acetaminophen overdose we heard about and spent a lot of time talking about yesterday . . . ." NDAC Transcript at 248. No one disagreed with his statement.

35. FDA Response at 5.

36. Id.

37. Id.

intentional, suggesting that many people are aware of acetaminophen risk. Second, the implication of FDA's argument is that NSAID risk is well-known to consumers. If that were true, presumably NSAID-related adverse events would be a less prevalent phenomenon. In fact, NSAID-related GI bleeds are far more frequent than acetaminophen-related liver toxicity.

Third, FDA says that the consequences of NSAID overdose are not on par with acetaminophen overdose.[38] FDA then explains that overdosing with acetaminophen for several days creates significant risk while overdosing with NSAIDs for several days does not create such a risk. That response misses two important points. For one thing, as discussed above, that an OTC overdose may also be a prescription dose of an NSAID does not change the fact that it is an OTC overdose. For another thing, the Campaign is about safe use of OTC analgesics in general, not just safe use over a period of a few days. Chronic overdoses of NSAIDs are the larger public health problem.

Fourth, FDA explains its mention of the alcohol warning on acetaminophen while ignoring the alcohol warning on NSAIDs by saying that NDAC questioned the need for an alcohol warning on NSAIDs, and that FDA has not decided whether to remove the requirement for an alcohol warning on NSAIDs.[39] FDA neglects to mention, however, that NDAC members also questioned the need for an alcohol warning on acetaminophen, and concluded that the alcohol warning should be addressed for both.[40] Further, the fact that FDA staff may internally be considering whether to continue to require a warning is not a reason to make alcohol a point of differentiation between acetaminophen and NSAIDs. FDA has not removed the warning on NSAIDs; it has not even proposed to do so; and it has heard no public comment on the issue. In short, the current thoughts of some agency staff should not trump the agency's position on this question.

FDA explains its omission of the Reye's Syndrome warning on similar grounds, saying that Reye's Syndrome is not a problem.[41] McNeil acknowledges the success of FDA's consumer education campaign on Reye's Syndrome. That, however, is no reason to abandon it; it is a reason to keep up the good work, and not to undermine a message that FDA has successfully communicated. Further, the omission of the Reye's Syndrome warning in this context is particularly problematic because FDA makes a point of the dangers of overdosing children with acetaminophen. As McNeil pointed out in the Complaint, frightening parents away from using

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38. Id.

39. FDA Response at 5-6.

40. NDAC Transcript at 268-270.

41. FDA Response at 6.

acetaminophen in children invites them to choose aspirin, heightening the need to remind consumers about Reye's Syndrome.[42]

(3) The State Boards of Pharmacy Memo, the Questions and Answers, and the Brochure

In the Complaint, McNeil suggested that these three pieces contain less obvious examples of how the Campaign elevates the risks of acetaminophen over those of NSAIDs.[43] Many of FDA's responses provide an explanation, but fail to grapple with the problem. For example, FDA's explanation of the use of the word "severe" to describe acetaminophen-related complications rests on the fact that NDAC was focused on severe acetaminophen complications.[44] The explanation, however, although it may be literally true, does not change the way a consumer is likely to understand the sentence – to mean that the acetaminophen-related complications are more severe than the NSAID complications. Similarly, FDA uses the word "rare" to describe NSAID complications, but not to describe acetaminophen-related complications, and explains that this was a deliberate effort to avoid discouraging consumers from using NSAIDs.[45] This is a laudable policy goal, but still has the effect of distorting the facts, since acetaminophen-related complications are even more rare. It would be a distraction from this request to reargue each of the points in these sections, and, therefore, McNeil has chosen not to do so. McNeil's original point, however, remains. Even the use of single words or phrases used to describe acetaminophen or inject a sense of urgency on particular thoughts can, as these do, make a piece sound as if FDA believes acetaminophen is more dangerous than NSAIDs.

Conclusion

In focusing its response primarily on individual examples of statements that contribute to the Campaign's lack of objectivity, FDA has missed the point of McNeil's Complaint. The point is that the Campaign as a whole, and certain elements of it, represent that acetaminophen is less safe than NSAIDs, as unequivocally demonstrated by the press response to the Campaign. Because acetaminophen is not less safe than NSAIDs, the Campaign is not objective, and is inconsistent with the mandate of the FDQA. For this reason, and for the other reasons explained above, McNeil requests that FDA reconsider the Complaint, and grant the relief requested therein.

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42. Complaint at 9-10. In its response, FDA points out that there was a separate FDA Consumer article on NSAID risk. FDA Response at 6. One must wonder why the acetaminophen article became part of the Campaign, whereas the aspirin article did not.

43. Complaint at 6.

44. FDA Response at 8.

45. Id.

McNeil would like very much to discuss these issues with you, and will call to schedule a time to do so in the next few weeks.

Sincerely,

Nancy L. Buc
Kate C. Beardsley

cc: Chief Mediator & Ombudsman (HF-7)
Food and Drug Administration