



May 10, 2004

5960  
04  
MAY 10 9:11

**BY HAND DELIVERY**

Division of Dockets Management  
HFDA-305  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

RE: Docket No. 2004D-0042 -- Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions -- Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements

Catalina Health Resource (CHR) is pleased to submit these comments to the Food and Drug Administration (FDA) on the Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions, 69 Fed. Reg. 6308 (Feb. 10, 2004). Specifically, CHR offers comments upon one of the three draft guidances FDA issued: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (Brief Summary Draft Guidance).

**EXECUTIVE SUMMARY**

FDA is to be commended for addressing in the Brief Summary Draft Guidance the issue of what information must accompany direct-to-consumer (DTC) print promotions of prescription drugs. The issue has been of great concern to those, like CHR, who are committed to improving the quality of consumer-directed print communications about prescription drugs. For too long technical risk information has been buried in tiny print disclosures alongside prescription drug print promotions.

The Brief Summary Draft Guidance is an important step in the right direction. CHR hopes to see FDA build upon this excellent foundation in the final guidance. In the final guidance, CHR proposes to see the following:

1. **Acknowledgement of and accommodation for in-pharmacy communications**  
– The final guidance should include recognition that the compliance and adherence communications that pharmacies disseminate to their patients are primarily educational, not “promotional.” These in-pharmacy, Direct-To-Patient (DTP) communications should not trigger accompanying information requirements (e.g., full professional labeling or brief summary).

2004 D-0042

C 20

2. **Alternatives if information must accompany DTP communications** – The final guidance should allow for all in-pharmacy DTP promotions to use an “adequate provision” disclosure model. In-pharmacy DTP promotions, among other things, would have to be fairly balanced, include a major statement of the risks of the prescription drug promoted, and describe the adequate provision that has been made for the patient to receive further information. Alternatively, pharmacies should be able to satisfy accompanying information requirements by providing the useful consumer medicine risk and usage information (or “CMI”) that accompanies the prescription drug.
3. **Extension of the guidance to allow a brief summary for all promotional labeling** – The final guidance should include a statement of the agency’s intention to exercise its enforcement discretion to allow a brief summary to accompany DTC prescription drug promotional labeling disseminated in a pharmacy in lieu of the full professional labeling;
4. **Clarification and refinement of brief summary content** – The final guidance should more clearly set out what information must be in a brief summary and should allow for more concise summaries of important risk information.
5. **“Less Is More”: Rx Drug Facts** – The final guidance should better embody the “less is more” approach advocated in FDA’s public statements. CHR suggests adoption of an “Rx Drug Facts” box approach similar to that so successfully used for other FDA-regulated products.

Discussion of these points follows.<sup>1</sup>

### **ABOUT CHR**

CHR fills a unique niche in the process by which a patient becomes informed about prescription drugs, initiates a conversation with his or her health care professional about a potential disease or condition, discusses prescription drug therapy, and, potentially, receives and fills a prescription. CHR publishes a Newsletter that provides a vehicle for communication in over 12,000 pharmacies nationwide, producing Newsletters with over 1.1 billion prescriptions for over 45 million patients per year. The pharmacist provides a customized educational CHR

---

<sup>1</sup> CHR has commented previously upon initiatives and guidances of FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC). We attach copies of a recent comment.

Letter to Division of Dockets Management

May 10, 2004

Page 3

Newsletter to the patient at the time he or she fills or refills a prescription. The CHR Newsletter is a folded piece of paper with content appearing on different panels of the printed page.

The first panel of the Newsletter will usually provide important consumer medicine information (CMI) about the proper use of the drug being dispensed to the patient, including the name of the drug, indications and instructions for use, drug interaction precautions, adverse reactions, and possible side effects. This section of the Newsletter is intended to satisfy the "useful patient information" criteria of Pub. L. No. 104-180 and the "Action Plan for the Provision of Useful Prescription Medicine Information" (commonly referred to as the "Keystone Criteria").<sup>2</sup> Typically, the pharmacy contracts with a well-known provider, such as First Data Bank or Medi-Span, who generates the CMI to accompany all of the pharmacy's dispensed prescriptions. Or, the pharmacy may utilize CHR to provide the CMI.

Other panels of the Newsletter contain additional content for consumers. There may be educational information about the prescribed medication or the condition the medication treats. The Newsletter may contain advice about how to take the drug properly, the benefits of the drug, and the importance of refilling prescriptions for drugs that treat chronic disease. The Newsletter also sometimes carries public service announcements and health messages from the FDA. Last, the Newsletter may carry disease/therapy awareness messages and communications about alternative or adjunctive prescription or over-the-counter (OTC) therapies.

The Newsletter is easily distinguishable from typical, ubiquitous DTC promotion. The pharmacy customer receives the Newsletter from his or her pharmacist (or possibly the pharmacist technician) in a face-to-face transaction. The pharmacy has reviewed the contents of the Newsletter to assure that it is accurate, consistent with its sound pharmacy practices, and is contributing to the pharmacy's communications with its patients. The Newsletter's content is also distinct from DTC promotion in that it is part of an ongoing health care dialogue between patients and their physicians and pharmacists.

---

<sup>2</sup> The Keystone Criteria require that useful written CMI must be: (1) scientifically accurate, (2) unbiased in content and tone, (3) sufficiently specific and comprehensive, (4) presented in an understandable and legible format that is readily comprehensible to consumers, (5) timely and up-to-date, and (6) useful.

## **DISCUSSION**

### **1. The Final Brief Summary Guidance Needs To Accommodate DTP Print Communications In Pharmacies**

#### **a. Pharmacy Communications Are Important and Should Not Burdened**

Pharmacies are being called upon to provide more and better information to their patients about their medicines. These activities include:

- **Mandatory pharmacy counseling.** In 1990, as part of the Omnibus Budget Reconciliation Act, Congress required pharmacists to offer to discuss with patients who receive benefits under Medicaid programs any information that the pharmacist deems significant, including a description of the medication; the duration of drug therapy; common severe side effects or interactions and therapeutic contraindications, and prescription refill information. 42 U.S.C. § 1396r-8(g). Most states subsequently adopted laws or rules that require counseling for all consumers.<sup>3</sup>
- **Dissemination of “useful written information.”** As mentioned previously, pursuant to Public Law No. 104-180 and the implementing Keystone criteria, pharmacies are providing useful, written CMI to consumers about the prescription drugs they are receiving.
- **Medication Management Therapy Programs.** The Medicare Improvement and Modernization Act of 2003 requires insurers providing prescription drug plans under the new Part D benefit to work with pharmacists to provide “medication therapy management programs” for individuals with multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure), who are taking multiple covered drugs and are likely to have high annual drug costs. 42 U.S.C. § 1395w-104(c). The requirement for these management programs is intended to ensure that covered drugs “are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.” 42

---

<sup>3</sup> Almost all states have “offer to counsel” or “mandatory counseling” requirements. *See e.g.*, Alabama (Ala. Admin. Code R. § 680-X-2-.21), Alaska (12 Alaska Admin. Code § 52.585), California (16 CCR § 1707.2), Delaware (CDR § 24-2500-5.3), Florida (F.A.C. § 64B16-27.820), Idaho (Idaho Code § 54-1749), Indiana (856 IAC § 1-33-2), Iowa (657 IAC § 6.14(155A)), Missouri (4 CSR § 220-2.190) and Tennessee (Tenn. Comp. R. & Regs. R. § 1140-3-.01).

U.S.C. § 1395w-104(c)(2)(A)(i). Products like the CHR Newsletter will help pharmacists meet the informational obligations under the new Part D Medicare program.

Unfortunately, these important goals are potentially being undermined and stifled by FDA's current interpretation of its prescription drug labeling regulations. Under DDMAC's application of current regulations to DTP communications, messages about the importance of complying with the prescribed therapy dispensed, if paid for by the drug manufacturer, are deemed to be promotional labeling. Promotional labeling triggers the requirement of providing the full *professional* labeling, even though the intended recipient is a *patient* who is already receiving CMI about the same dispensed drug.

In CHR's experience, pharmacists are very reluctant to provide the full product labeling or brief summary to their patients. Of concern to pharmacists is the length and technical complexity of the full product labeling or brief summary – the document prints on several pages at the pharmacy printer. Pharmacists are concerned that patients will not understand the reasons for the extensive risk disclosures relative to the benefits of the drug, and discontinue therapy. Busy pharmacies also worry that pages will be lost or, far worse, mixed up or given to the wrong patient, with potentially severe repercussions to their patients.

For these very compelling reasons, we believe a sound basis exists for exempting certain DTP communications from FDA accompanying information requirements altogether.

**b. DTP Compliance And Adherence Communications Should Not Trigger Accompanying Information Requirements**

CHR urges FDA to reconsider the applicability of its promotional labeling requirements to pharmacy dissemination of information about the drug dispensed to the patient. We believe that such a communication should not be regulated as promotional when it:

- Concerns the dispensed drug and;
- Conveys compliance or adherence information (e.g., “Be sure to take Drug X every day, even if you begin to feel better; tell your doctor right away if you [identify serious side effects/warnings from professional labeling]”).

For the reasons stated below, we believe these DTP compliance/adherence messages should not trigger accompanying information requirements because they are not “promotional.”<sup>4</sup>

First, serious problems are arising in health care from patient non-compliance with prescription medicines.<sup>5</sup> There are sound public health reasons for encouraging DTP messages that communicate the importance of adhering to prescribed therapies. Determining that these types of communications are not promotional is one way that DDMAC can encourage pharmacies to disseminate more compliance/adherence communications.

Second, other agencies of the United States government have looked at the same issue and found that the benefits of compliance/adherence health care messages are so compelling, they warrant special distinction and support. Specifically, the Department of Health and Human Services (HHS) Privacy Rule implementing the Health Insurance Portability and Accountability Act (HIPAA) deems refill reminder and similar adherence/compliance communications to be “treatment,” rather than “marketing.” 67 Fed. Reg. 53,182, 53,184 (Aug. 14, 2002). In the view of HHS, these communications are not marketing even though a pharmaceutical company

---

<sup>4</sup> We note that in DDMAC’s view, accompanying information *is not* triggered for an FDA-sponsored public service announcement (PSA) attached to the drug the pharmacy dispenses that states: “Take your medicine at the same time each day to help get the most out of your therapy.” However, accompanying information may be triggered if a drug’s manufacturer sponsors the nearly identical message: “Take Statin Brand X at the same time each day to get the most out of your therapy.” CHR believes FDA should be looking to the content of the message (educational/informative or promotional), and not who sponsors it.

<sup>5</sup> The public health benefits of *compliance and adherence* messages are widely recognized. For example, patients who do not comply with drug regimens as prescribed face increased hospital or nursing home admissions, lost workdays, and even death. One recent study estimated that the direct and indirect costs to society resulting from patients who do not adhere to prescribed drug therapy are about \$177 billion annually. Ernst FR and Grizzle AJ, “Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model,” 41 *Journal of the American Pharmaceutical Assn* 192 (March/April 2001). See also Berg, *et al.*, *The Annals of Pharmacotherapy*, 27 (9): S3-S22 (1993) (estimating that patients who do not adhere to drug therapy cost the U.S. health care system an additional \$100 billion each year). In January 2003, the World Health Organization issued a major report that stated “[i]ncreasing the effectiveness of adherence interventions may have a far greater impact on the health of [a given] population than any improvements in specific medical treatments.” World Health Organization (WHO), “Adherence To Long-Term Therapies: Evidence For Action” (2003) at 21. See also “The Real Drug Problem: Forgetting to Take Them,” *Wall Street Journal*, October 21, 2003, Section D, p. 1; <http://www.medicines-partnership.org/research-evidence/major-reviews>.

Letter to Division of Dockets Management  
May 10, 2004  
Page 7

sponsors them. HHS deems the benefits of reinforcing the importance of compliance with prescribed regimens to be too important to risk limiting these communications by imposing restrictions that would chill these disseminations if they were characterized as marketing.

Last, in-pharmacy communications differ significantly from traditional DTC print promotion in magazines and newspapers. DTP communications are disseminated as part of a face-to-face and ongoing interaction between the pharmacist (or pharmacy technician) and the pharmacy customer. In the case of communications received in the pharmacy, such as the CHR Newsletter, the pharmacist is physically present and available to answer the patient's questions and/or provide additional information (such as a copy of the full labeling) if the patient requests it. In-pharmacy DTP communications are also part of the ongoing process of a patient's health care. A physician has already seen the patient, diagnosed a disease or condition, and prescribed a medicine and course of therapy. The pharmacy has prepared a message complimenting that therapy and tailored that message for that particular patient. The pharmacy's communications reinforce the physician's advice to the patient and the CMI that the pharmacist is providing. In fact, CHR submits that this type of messaging is really more analogous to reminder and awareness messages, both of which are exempt from accompanying information requirements. *See e.g.*, 21 C.F.R. § 202.1(e)(2)(i).

In contrast, traditional print promotions are not presented to the patient in an established health care environment or even within the context of an ongoing and pre-existing health care dialogue. Traditional promotional messages are not tailored to the patient. No pharmacist is present when the individual receives the communication. Also, the individual may not have an existing relationship with a physician regarding the disease or condition discussed in the communication.

For all these reasons, we believe that a compelling argument is made that these valuable in-pharmacy DTP communications messages should not be deemed promotional and should not need accompanying information. At a minimum, we urge FDA to consider the serious potential for patient harm that can arise if in-pharmacy DTP communications must be accompanied by multiple pages of highly technical risk information.

Should, however, FDA continue to require that in-pharmacy DTP compliance/adherence communications include accompanying information we suggest DDMAC exercise its enforcement discretion and allow alternative methods for conveying that information. We enumerate options for all in-pharmacy DTP prescription drug communications below.

## **2. Alternatives If Information Must Accompany DTP Communications**

CHR suggests two options for conveying accompanying information with in-pharmacy DTP communications. First, CHR suggests DDMAC permit "Keystone compliant" CMI (discussed above) to satisfy the accompanying information requirement. When the consumer receives the medicine, the CMI provides the important risk information and explains how to take the medicine safely. We recognize that what constitutes adequate and compliant CMI is still subject to development and discussion. However, there is significant overlap between the elements of the CMI Keystone criteria and the elements of sufficient brief summary that DDMAC sets forth in the draft guidance. To require the brief summary to repeat the same risk information that is in the CMI would be duplicative.

As a second alternative, CHR asks DDMAC to apply the Guidance for Industry -- Consumer-Directed Broadcast Advertisements (August 1999), to in-pharmacy DTP communications. A broadcast advertisement must, among other things:

- Present a fair balance between information about effectiveness and information about risk;
- Include a major statement conveying all of the product's most important risk information in consumer-friendly language; and
- Describe the "adequate provision" the sponsor had made for the dissemination of the drug's product labeling through such means as asking pharmacists and physicians, calling a toll-free number, visiting a website, or referring to a traditional print advertisement.

CHR continues to believe that this "adequate provision" model is especially appropriate for in-pharmacy DTP communications. Space now devoted to recitation of lengthy and technical accompanying information could be devoted instead to useful and relevant information for the patient. With the communication occurring within the pharmacy, vehicles such as the Newsletter can refer the patient to at least four different places for additional information:

- The pharmacist, from whom the patient has received the communication;
- The physician, with whom the patient already has a relationship;
- A website address;
- A toll free number; and
- The FDA-approved patient labeling (if it exists) and/or professional labeling.

CHR is in good company in advocating the "adequate provision" model. The Federal Trade Commission (FTC) has also suggested in comments that FDA adopt this model for all DTC print advertising:

We believe that the FDA should replace the requirement that the DTC print ads include the FDA-approved product labeling with the requirement that such ads include a major statement of risks with adequate provision for consumers to receive more complete risk information from other sources. To increase consumer comprehension of important risk information in DTC ads, it is important to display the information in a clear and easily understandable format. By presenting the information in a more accessible format and form, this approach will make it more likely that consumers will actually see and understand the risk information provided. This change would make the brief summary requirement for DTC print ads consistent with the brief summary requirement for DTC broadcast ads.

Docket No. 2003N-0344, Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission (Dec. 1, 2003) at 24-25.<sup>6</sup>

FDA did not adopt the broadcast adequate provision model in the Brief Summary Draft Guidance. We ask that FDA reconsider that decision, at least for DTP communications.

### **3. A “Brief Summary” For All DTC Promotional Labeling**

While CHR recognizes that the Brief Summary Draft Guidance is addressing advertising, we urge FDA to extend the Draft Guidance’s commendable goals a fraction further. As discussed, consumers receive prescription drug information in print from many sources other than traditional newspapers and magazines. In addition to in-pharmacy DTP communications about the drug dispensed to the patient, consumers may receive brochures, pamphlets, coloring books, questionnaires, slim jims, and other material about a prescription drug. These materials are written for the consumer, and even the pediatric patient, and are not intended for the medical professional. Under traditional DDMAC distinctions these materials are “promotional labeling,” and would be required to include the full professional labeling.

Consumers are not served by rigid adherence to a technical requirement that mandates the provision of information not written for them. CHR asks that FDA state in the final guidance that the agency will exercise its discretion and not take enforcement action against promotional

---

<sup>6</sup> Other commentators have suggested this approach as well, including the National Consumers League.

labeling directed to consumers if the information that accompanies the promotion otherwise conforms to the brief summary principles set out in the guidance.

**4. FDA Should Clarify And Simplify What Information  
Must Be In A Brief Summary To Comply With The Guidance**

The Brief Summary Draft Guidance sets out three alternatives for new brief summaries:

- A consumer-friendly version of the information that, under a proposed regulation, would appear in a “Highlights” box in the approved labeling.<sup>7</sup>
- All risk information from the FDA-approved professional labeling.
- FDA-approved patient labeling, either in its entirety or as modified to omit less important risk information.

Brief Summary Draft Guidance at 94-98. As some confusion has arisen regarding when DDMAC will exercise its enforcement discretion, CHR asks that the final guidance incorporate greater clarity and allow for more concise summaries of risk information.

**a. Tying Brief Summary To The “Highlights” Box**

CHR supports the Highlights box approach as truly attempting to make the brief summary more useful. Unfortunately, CHR sees several short- and medium-term problems with tying the brief summary content to the Highlights box:

- What will be in that Highlights box, and indeed, whether there will be a Highlights box at all, depends upon FDA finalizing the Revised Labeling Proposed Rule. That rulemaking has been pending for several years. While we understand that FDA intends to finalize this rule shortly, such projections are often revised, as new demands arise for an agency with limited resources.
- The Brief Summary Draft Guidance assumes that there will be an FDA-approved Highlights box available for most drugs once the revised labeling rule becomes final. Brief Summary Draft Guidance, 231-236. However, it will be several years before the majority of currently marketed drugs have a Highlights box.

---

<sup>7</sup> The Highlights Box is a concept that appeared in FDA’s proposed rule to revise the format and content of prescription drug labeling. *See Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirement for Prescription Drug Product Labels*, 65 FR 81082 (Dec. 22, 2000) (Revised Labeling Proposed Rule).

- Tying the content of the brief summary to documents that do not yet exist creates uncertainty for drug sponsors. No one wishes to risk enforcement action, and so most may be unwilling to embrace the Highlights box for DTC print promotions until FDA provides clearer direction.
- The Brief Summary Draft Guidance seems to state plainly that while the labeling rule is pending, a manufacturer can “provide the risk information that would be appropriate for FDA-approved Highlights.” Brief Summary Draft Guidance at 97-98. However, there is a belief among many in the industry that DDMAC does not wish to see brief summaries based upon what would be in a theoretical Highlights box until the labeling rule is final and FDA has approved the drug’s revised labeling. CHR respectfully asks that FDA provide a clear statement that a consumer-friendly version of a theoretical Highlights box is an option for a brief summary. Unless it does so, the final Guidance would, in effect, only be allowing two options for a brief summary: the full professional labeling or the FDA-approved patient labeling.

**b. Greater Clarity Regarding What Must Be In A Compliant Brief Summary**

Regardless of the document on which the brief summary is based, the draft guidance specifies that the brief summary must include the following elements:

- Contraindications: all;
- Warnings: all;
- Precautions: the major precautions, including any that describe serious adverse drug experiences (as defined in 21 CFR § 312.32(a) & § 314.80(a)) or steps to be taken to avoid such experiences; and
- Adverse Reactions: the 3-5 most common nonserious adverse reactions most likely to affect the patient’s quality of life or compliance with drug therapy

Brief Summary Draft Guidance at 171-177, 193-199, 216-222. We believe there are several difficulties with this formula and ask DDMAC for greater flexibility in the final guidance.

**i. Omission Of Certain Categories Of Risk Information**

First, we note that the Brief Summary Draft Guidance could be understood as *more restrictive* than the previous, and now withdrawn, brief summary reform FDA announced in *Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements*, 66 Fed. Reg. 20468 (April 23, 2001). That draft guidance would have permitted a brief summary to *omit* the following:

- Side effects that are not serious and do not occur frequently or that are unlikely to be the result of taking the product
- Information related to carcinogenesis, mutagenesis, and infertility that does not warrant a discussion under the Warnings section
- Information related to pregnancy that does warrant a D or X pregnancy category
- Information related to use in labor, delivery, breast-feeding, pediatric, and other special populations that does not warrant a discussion under the Warnings section.

CHR asks that the final brief summary guidance clarify that the above information may be omitted.

#### **ii. Omission Of Information Not Related To Risks**

Lines 189 – 190 of the Brief Summary Draft Guidance state that a brief summary based upon a drug’s FDA-approved patient labeling may be “modified to include only risk information (e.g., by deleting instructions for use).” In contrast, the Ocracephalose example DDMAC provided with the draft guidance includes additional information not related to risk.

We ask that FDA harmonize the elements for the different brief summary formats and make clear that the essential purpose is to advise the patient of the most common and most serious risks. CHR suggests that the final guidance allow omission from the brief summary of information not related to risk, including:

- Indication
- Dosage
- Usage instructions
- How supplied
- Disease/diagnostic information
- Laboratory tests and other physician monitoring
- Overdosage

All of this information is obviously important to safe use of the drug, but is more appropriately delivered during a physician’s consultation with the patient and/or in the CMI dispensed with drug, should the physician prescribe it. Presented in a brief summary, such information detracts from the important risk information that should dominate the brief summary.

#### **iii. Provision Of A Formula That Will Allow For “Less Is More”**

In the briefing that accompanied the release of the Brief Summary Draft Guidance, in the FDA press release, and in subsequent briefings, FDA officials have emphasized that the intent of

the Brief Summary Draft Guidance was to capture a “less is more” approach. Unfortunately, it is proving difficult to create new, concise, plain language brief summaries using the formula FDA set out in the draft guidance (all contraindications, all warnings, major precautions). Certainly for some drugs, such as the Ocracephalose model, the risk information is fairly straightforward and can be boiled down to a useful, concise summary. For other drugs, however, translating all the contraindications, warnings, and major precautions into consumer-friendly language and format is lengthening the brief summary, not shortening it.

For instance, a brief summary for a typical oral contraceptive would likely extend for a full, three-column page of a magazine, in very, very tiny, dense type. Of those three columns, relatively little space is devoted to adverse reactions that, under the Brief Summary Draft Guidance, may be limited to the three to five most common, non-serious side effects. Dozens of contraindications, warnings, and precautions take up nearly an entire page of the magazine. Converting this type of risk information into a new brief summary with larger, more legible type and consumer-friendly language would likely require several more pages in the magazine.

Drugs with numerous drug/drug interactions are posing a similar difficulty. CHR submits that each drug interaction need not be identified so long as the brief summary plainly discloses the clinically significant, dangerous interactions, and that the information is not complete. The interaction statement should also include a general caution, such as “Tell your doctor about all prescription and OTC drugs you take, and any vitamins/minerals, herbal or natural products.”

CHR also recommends the final guidance focus upon key pieces of risk information, emphasizing clarity and comprehension over completeness. CHR believes that it would be very useful if FDA provided a formula, decision tree or algorithm for summarizing risk information. CHR recommends the following essential elements:

- The brief summary must make clear that the information is not complete;
- The brief summary must advise the consumer where he or she can go to obtain more information;
- The risk information in the brief summary should include:
  - All consumer-relevant black box warnings
  - *A concise summary of the contraindications* describing those situations in which the drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit<sup>8</sup>
  - *The clinically significant drug interactions proven dangerous to humans*<sup>9</sup>

---

<sup>8</sup> This requirement is derived from FDA’s Revised Labeling Proposed Rule regarding what contraindications must be included in the Highlights box. 65 Fed. Reg. at 81114, 81116.

- Three to five of most common nonserious adverse reactions most likely to affect the patient's quality of life or compliance with drug therapy
- *A concise summary of the most clinically significant warnings and precautions*<sup>10</sup>

**iv. "Less Is More" – Rx Drug Facts**

For several years, CHR has advocated that DDMAC consider an Rx Drug Facts box as a potential alternative to the traditional brief summary. As envisioned, the Rx Drug Facts box would follow the lead of other highly successful FDA initiatives and standardize the presentation of important information about an FDA-regulated product, in this case, a prescription drug. FDA has significant data demonstrating consumer acceptance and use of the "Facts" boxes for other products, including foods, dietary supplements and OTC drugs. The basic Facts format has been subject to extensive testing and consensus rulemaking.

The Rx Drug Facts box would, necessarily, be abbreviated and favors consistency and comprehension over completeness. Its point is not to convey every bit of information in a drug's professional labeling. Rather, it would build upon FDA's Revised Labeling Proposed Rule that focuses upon a concise summary of the most clinically significant risks, and the most common, non-serious adverse reactions. An Rx Drug Facts box would also need to incorporate other, more complete information by reference, including website links, toll-free numbers, and brochures in doctors' offices and pharmacies.

Other commentators have supported the concept of an Rx Drug Facts box, including the National Consumers League and presenters at the FDA public meeting on DTC promotion in September 2003. We attach samples of the Rx Drug Facts format for your review. We intend to conduct consumer testing of this and other brief summary formats. We look forward to sharing this data with DDMAC.

\* \* \*

---

<sup>9</sup> Looking to the FDA's Revised Labeling Proposed Rule, that rule would not require identification of drug interactions supported only by animal or in vitro data, unless such data were clinically relevant. 65 Fed. Reg. at 81117.

<sup>10</sup> This requirement is derived from FDA's Revised Labeling Proposed Rule regarding what warnings/precautions must be included in the Highlights box. 65 Fed. Reg. at 81114.

Letter to Division of Dockets Management  
May 10, 2004  
Page 15

CHR thanks FDA for this opportunity to comment. We look forward to working with the agency to achieve the goals of empowered consumers who are knowledgeable about their healthcare choices.

Sincerely,

A handwritten signature in black ink that reads "Craig Scott / 18". The signature is written in a cursive, slightly slanted style.

Craig Scott  
President  
Catalina Health Resource

/lss  
Attachments

cc: Daniel E. Troy, Esq.  
Food and Drug Administration  
(By Federal Express)

RLF

OLSSON, FRANK AND WEEDA, P. C.

PHILIP C. OLSSON  
RICHARD L. FRANK  
DAVID F. WEEDA (1948-2001)  
DENNIS R. JOHNSON  
ARTHUR Y. TSIEN  
JOHN W. BODE\*  
STEPHEN D. TERMAN  
MARSHALL L. MATZ  
MICHAEL J. O'FLAHERTY  
DAVID L. DURKIN  
NEIL F. O'FLAHERTY  
PAMELA J. FURMAN  
BRETT T. SCHWEMER

ATTORNEYS AT LAW  
SUITE 400  
1400 SIXTEENTH STREET, N.W.  
WASHINGTON, D. C. 20036-2220  
(202) 789-4212  
FACSIMILE (202) 234-3550

TISH E. PAHL  
ROBERT A. HAHN  
NAOMI J. L. HALPERN  
STEPHEN L. LACEY  
SHARON D. BROOKS  
RYAN W. STROSCHEIN  
EVAN P. PHELPS  
VALERIE B. SOLOMON\*

Mr. Frank's Direct Phone (202) 518-6363  
Mr. Frank's Direct Facsimile (202) 234-2686

Mr. Bode's Direct Phone (202) 518-6323  
Mr. Bode's Direct Facsimile (202) 234-1560

OF COUNSEL  
JUR. T. STROBOS  
JACQUELINE H. EAGLE  
KENNETH D. ACKERMAN  
MARK L. ITZKOFF

\*PRACTICE WITHIN THE DISTRICT OF COLUMBIA  
IS LIMITED TO MATTERS AND PROCEEDINGS  
BEFORE FEDERAL COURTS AND AGENCIES

November 17, 2003

**BY FEDERAL EXPRESS**

Daniel E. Troy, Esq. (GCF-1)  
Chief Counsel  
Food and Drug Administration  
5600 Fishers Lane, Room 657  
Rockville, Maryland 20857

Thomas W. Abrams, R.Ph., MBA (HFD-42)  
Director of Drug Marketing, Advertising & Communications  
Food and Drug Administration  
5600 Fishers Lane, Room 8B45  
Rockville, Maryland 20857

Re: A Change to Accompanying Information For In-Pharmacy  
Direct-to-Patient Communications – A Prescription For Reform

Dear Messrs. Troy and Abrams:

We are writing to you on behalf of our client Catalina Health Resource (CHR) regarding the need for reform of current Food and Drug Administration (FDA) interpretations that require all prescription drug print promotions to be accompanied by a brief summary (if "advertising") or full labeling (if "promotional labeling"). As FDA moves to issue a draft guidance on reform of accompanying information requirements for direct-to-consumer (DTC) prescription drug promotion, we urge the agency to recognize and address the special issues that in-pharmacy direct-to-patient (DTP) communications raise.

**Executive Summary: Prescription for Reform –  
In-Pharmacy DTP Communications**

- Exempting In-Pharmacy DTP Communications
  - CHR believes that the traditional accompanying information requirements for print promotions should not be imposed upon in-pharmacy DTP communications, particularly educational compliance/adherence messages. In-pharmacy DTP

Letter to Daniel E. Troy, Esq.  
Thomas W. Abrams, R.Ph., MBA  
November 17, 2003  
Page 2

communications are distinguishable from common DTC print promotion on many grounds – the face-to-face interaction in the health care environment; the patient's existing relationship with a physician and a pharmacist; the pharmacist's involvement in the message communicated; and the limitations existing within the pharmacy itself. For these reasons, in-pharmacy DTP communications messages should not trigger accompanying information requirements at all.

- If, however, FDA continues to adhere to the policy that even in-pharmacy DTP communications must include accompanying information, CHR proposes that FDA look to alternatives to satisfy these requirements.
- Compliance or adherence messages
  - FDA should recognize that it serves no useful purpose to require in-pharmacy communications to include the full product labeling when the communication is a compliance or adherence message for the drug being dispensed. The dispensed drug is already accompanied by "useful written information," which should serve as the accompanying information. Providing the full package labeling intended for health care professionals is certainly not useful to consumers.
- Adjunctive/alternative therapy and awareness messages
  - When adjunctive/alternative therapy or awareness messages accompany the drug being dispensed in a face-to-face encounter in the pharmacy, there is no need or use for the brief summary.
  - Alternatives should be considered to the brief summary for in-pharmacy DTP communications – the most straight forward and logical of which is to apply the same standards used for broadcast ads. Under this approach, "adequate provision" would be satisfied by making a variety of information (full product labeling, patient labeling) readily and easily available via a toll-free number, a website address, and, most importantly for this type of unique communication, from the pharmacist during this face-to-face interaction.

**Catalina Health Resource, The Pharmacy Newsletter,  
And In-Pharmacy DTP Communication**

CHR fills a unique niche in the process by which a consumer becomes informed about his or her prescription drugs. CHR currently helps over 15,000 pharmacies publish a customized pharmacy Newsletter that provides a vehicle for communication between the pharmacies and their millions of patients.

Letter to Daniel E. Troy, Esq.  
Thomas W. Abrams, R.Ph., MBA  
November 17, 2003  
Page 3

The pharmacy, using CHR software, provides a customized educational Newsletter to the patient at the time he or she fills or refills a prescription. We provide several samples for your review. (Attachment 1) The first panel of the Newsletter typically provides important information about the proper use of the drug dispensed to the patient, including the name of the drug, indications for use, drug interaction precautions, adverse reactions, and possible side effects. This section of the Newsletter is intended to satisfy the "useful written information" criteria of Pub. L. No. 104-180 and the "Action Plan for the Provision of Useful Prescription Medicine Information." Typically, the pharmacy contracts with an independent information provider, such as First Data Bank, which generates the "useful written information" to accompany all of the pharmacy's dispensed prescriptions.

Other panels of the Newsletter provide additional *educational* messages for the patient. There may be information about the prescribed medication or the disease or condition the medication treats. Frequently, the Newsletter contains *compliance and adherence* advice about how to take the drug properly, and information about the importance of completing the course of treatment prescribed by the physician, as well as the importance of having prescriptions refilled (again, in accordance with the physician's directions). The public health benefits of these *compliance and adherence* messages are widely recognized. For example, patients who do not comply with drug regimens as prescribed face increased hospital or nursing home admissions, lost workdays, and even death.<sup>1</sup>

The Newsletter may also carry educational information about general disease states, information about alternative or adjunctive treatments to the prescribed therapy (including the option of generic drugs), "awareness" messages about related conditions, information referred to as "health tips," and information about over-the-counter drugs and consumer products. Recently, the Newsletter has started carrying *public service announcements* and health messages FDA has developed. (See Attachment 1 Atenolol Newsletter)

The Newsletter is easily distinguishable from typical, ubiquitous DTC promotion. The pharmacy customer receives the Newsletter from his or her pharmacist (or possibly the pharmacy technician) in a face-to-face transaction. Importantly, the pharmacy has reviewed the contents of the

---

<sup>1</sup> One recent study estimated that the direct and indirect costs to society resulting from patients who do not adhere to prescribed drug therapy are about \$177 billion annually. Ernst FR and Grizzle AJ, "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," 41 *Journal of the American Pharmaceutical Assn* 192 (March/April 2001). See also Berg, et al., *The Annals of Pharmacotherapy*, 27 (9): S3-S22 (1993) (estimating that patients who do not adhere to drug therapy cost the U.S. health care system an additional \$100 billion each year). In January 2003, the World Health Organization issued a major report that stated that "[i]ncreasing the effectiveness of adherence interventions may have a far greater impact on the health of [a given] population than any improvements in specific medical treatments." World Health Organization (WHO), "Adherence To Long-Term Therapies: Evidence For Action" (2003) at 21. See also "The Real Drug Problem: Forgetting to Take Them," *Wall Street Journal*, October 21, 2003, Section D, p. 1 (Attachment 2).

Letter to Daniel E. Troy, Esq.  
Thomas W. Abrams, R.Ph., MBA  
November 17, 2003  
Page 4

Newsletter to assure that it is accurate, consistent with their sound pharmacy practices and contributing to the pharmacy's communications with its patients. Moreover, the in-store pharmacist determines whether or not it is medically appropriate for his or her patient to receive a particular Newsletter. The Newsletter's content is also distinct from DTC promotion in that it is part of an educational program to encourage patients who already have existing relationships with a physician and a pharmacist to comply with their prescribed and dispensed regimens. Finally, the Newsletter, with its check lists, health tips, and other educational content, fosters more informed discussions between patients and their physicians and pharmacists.

**FDA's Accompanying Information Requirements  
And The Need For Reform**

Print advertising for prescription drugs must be accompanied by a "brief summary" of the drug's side effects, warnings, and contraindications. 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(3)(iii). Although not explicitly set forth in any agency regulation, FDA interprets its regulations so that print promotional labeling (promotional material that "accompanies" the drug) must be accompanied by the drug's full professional labeling, even when the promotional labeling is directed to consumers, rather than health care professionals.

FDA has announced that it intends to publish a new guidance to reform these accompanying information requirements. We note there is little dispute on the need for reform of accompanying information requirements for DTC prescription drug promotion overall. In comments submitted to FDA in 2002 on First Amendment issues, and again as recently as September 2003 at the DTC promotion public meeting, there was near unanimous agreement that the typical brief summary for print promotion is overly long, too technical, too difficult to read, and not useful to consumers. Requiring that DTC print communications be accompanied by the full product labeling intended for medical professionals is even less meaningful for consumers.

While reform of accompanying information is an admirable and important step in improving the quality of DTC print promotions, CHR is concerned that in-pharmacy DTP communications will be swept within the ambit of this broader DTC print guidance. For in-pharmacy DTP communications, such as the Newsletter, inclusion of the full package labeling or brief summary poses unique and significant obstacles. We believe in-pharmacy DTP communications should be addressed in the new guidance, but in a manner that recognizes their benefits and distinguishes them from ubiquitous DTC print promotions.

**FDA's Traditional Accompanying Information Requirements  
Should Not Be Applied To The In-Pharmacy Newsletter**

CHR believes that the traditional accompanying information requirements for print promotions should not be imposed upon in-pharmacy DTP communications, particularly those involving compliance/adherence messages.

Letter to Daniel E. Troy, Esq.  
Thomas W. Abrams, R.Ph., MBA  
November 17, 2003  
Page 5

First, strict application of the agency's accompanying information requirement has a stifling effect on the valuable messages communicated by the Newsletter. The Newsletter typically consists of a tri-folded 8½ by 14 inch sheet of paper. Because of space limitations, it is not possible for the full labeling – or even the full brief summary – to appear in the Newsletter.

Second, in CHR's experience, there are significant barriers to providing the full product labeling or typical brief summary with in-pharmacy DTC communications that extend well beyond the concern of too little space in which to fit, legibly and coherently, all the accompanying information. The chief opposition arises from the pharmacists themselves. Pharmacists are very reluctant to provide the full product labeling or brief summary to their patients, even though they may have the capability to print it separately on in-store computers. Of concern to pharmacists is the length and complexity of the full product labeling or brief summary, as the documents typically print on several pages at the pharmacy printer. Busy pharmacists worry that pages will be lost or, far worse, mixed up or given to the wrong patient, with potentially severe repercussions to their patients.

Pharmacists are also very concerned that if their patients review full product labeling or brief summaries, they will not understand the reasons for the extensive risk disclosures relative to the benefits of the drug, and will not fully adhere to or will discontinue therapy. While pharmacists will, of course, provide the full product labeling or brief summary when a patient asks for it, they try to provide that information within an appropriate context so that their patients are better informed without being frightened away from their prescribed and dispensed therapies. For these very compelling reasons, it has been CHR's experience that pharmacists are very reluctant to provide full product labeling or brief summaries with their routine, in-pharmacy DTP communications.

Third, the accompanying information requirements that apply to traditional print promotion should not automatically apply to in-pharmacy communications because vehicles such as the Newsletter are very different from traditional DTC print promotion in magazines and newspapers. As discussed above, the Newsletter is disseminated as part of a face-to-face interaction between the pharmacist (or pharmacy technician) and the pharmacy customer at the time the customer picks up the prescription. The pharmacist is physically present when the consumer receives the Newsletter and is available to answer the patient's questions and/or provide additional information (such as a copy of the full labeling) if the patient requests it.

Additionally, in-pharmacy DTP communications such as the Newsletter are uniquely personalized: the pharmacy has prepared the message that appears in the Newsletter; that message has been tailored and targeted to that particular patient; and the pharmacist or technician presents that message personally to the patient. For example, an individual filling a prescription for a beta-blocker may receive a Newsletter that includes information about the importance of adhering to the prescribed therapy. (*See Attachment 1, Atenolol Newsletter*) The Newsletter may also contain information about generic drugs (*See Atenolol Newsletter*) or the potential benefits to the patient of sound nutritional habits and exercise. In short, a physician has already diagnosed the disease or condition the Newsletter discusses and the individual can ask questions or obtain information from

Letter to Daniel E. Troy, Esq.  
Thomas W. Abrams, R.Ph., MBA  
November 17, 2003  
Page 6

his or her existing physician or pharmacist about the condition, drug, or information the Newsletter describes.

In contrast to the Newsletter, traditional print promotions are not presented to the patient in an established health care environment or even within the context of an ongoing and pre-existing health care dialogue. Traditional promotional messages are not highly targeted. No pharmacist is present when the individual receives the communication. Also, the individual may not have an existing relationship with a physician regarding the disease or condition discussed in the communication.

Fourth, in contrast to DTC print advertising where the sponsoring pharmaceutical company controls the message's content, with in-pharmacy DTP communications, the pharmacy has final say regarding the message's content and the pharmacist makes the ultimate determination of whether to give the message to his or her customer. In-pharmacy DTP communications are disseminated by or on behalf of a licensed pharmacist who acts as the "learned intermediary" between the pharmaceutical company and the consumer. Indeed, recognizing their public health benefit, the Department of Health and Human Services' HIPAA Privacy Rule specifically defines refill reminder and other similar educational communications as "treatment" rather than "marketing," even when a manufacturer or other third party sponsors the message. 67 Fed. Reg. 53,182, 53,184 (Aug. 14, 2002).

For all these reasons, we believe that a compelling argument is made that these valuable, educational in-pharmacy DTP communications messages should not trigger accompanying information requirements at all. We urge FDA to consider the serious potential for patient harm that can arise if in-pharmacy DTP communications must be accompanied by multiple pages of highly technical risk information. Compliance and adherence messages, in particular, should be exempt from accompanying information requirements given their educational content and contribution to a patient's overall treatment plan. However, if FDA continues to require accompanying information for in-pharmacy DTP promotions, we propose below alternative methods for conveying that information.

**"Useful Written Information" Should Serve As The Accompanying Information  
For In-Pharmacy Communications For The Drug Being Dispensed**

Nowhere are the accompanying information problems for in-pharmacy communications more apparent than when the Newsletter contains a compliance, or adherence message for the drug the pharmacist dispenses to the patient. We attach as an example a Newsletter for ACTOS®. (Attachment 3) On the first panel of the Newsletter is the "useful written information" intended to comply with Public Law No. 104-180. This is the information the patient needs to know to take ACTOS® safely and effectively. On another panel of the Newsletter is a short message discussing the importance of following the doctor's course of treatment for glycemic control by taking ACTOS® in a timely manner, keeping with a diet and exercise plan, filling and refilling prescriptions and informing the physician of adverse events. Because such messages *may* be considered by FDA

Letter to Daniel E. Troy, Esq.  
Thomas W. Abrams, R.Ph., MBA  
November 17, 2003  
Page 7

to be “promotional” in nature (we believe such messages instead should be deemed educational), the FDA-approved patient labeling for ACTOS® is presented.<sup>2</sup>

Plainly, the Newsletter contains *redundant information*, as risk information is repeated several times in a single document. This is the result of an agency policy that does not look at messages such as in-pharmacy DTP communications within the context in which they are presented to the consumer. When viewed as a whole, information throughout the Newsletter accompanies and supplements the message, to address the safe and effective use of the drug being dispensed.

For in-pharmacy DTP communications that bear messages for the drug being dispensed (compliance/adherence messages in particular), we suggest that FDA recognize in the draft guidance that the “useful written information” fulfills accompanying information requirements. This “useful written information” is sufficient to inform a patient who is actually taking the drug. It therefore follows that this same quantum of information is appropriate to accompany a message that supports and reinforces the overall treatment plan a physician has already prescribed.

**The “Adequate Provision” Approach Should Be Permitted  
As Accompanying Information For In-Pharmacy DTP  
Communications About A Drug Other Than The One Dispensed**

The Newsletter may also contain messages for a drug other than the one dispensed. These messages may direct the consumer to information about adjunctive therapies (*e.g.*, for a dispensed allergy nasal spray, there may be a message for a non-sedating antihistamine). The Newsletter may have a message building awareness of diseases that may be associated with the condition for which the drug is prescribed, *e.g.*, diabetes information accompanying a statin drug. Or, the Newsletter may have a message suggesting that the customer speak to his or her doctor about an alternative therapy. Under FDA’s current policies, these messages trigger the brief summary. We enclose examples of these awareness, adjunctive and alternative therapy messages. (Attachment 4)

The most straightforward alternative to the brief summary otherwise required for this type of communication is to hold such communications to the same standard as broadcast advertising, as described in FDA’s Guidance for Industry – Consumer-Directed Broadcast Advertisements (August 1999).<sup>3</sup> The awareness, adjunctive or alternative therapy communication should be fairly balanced, include a major statement of risks, and, most importantly, take advantage of the fact that the consumer is already in the pharmacy. An in-pharmacy adjunctive, awareness, or alternative therapy

---

<sup>2</sup> This sample Newsletter was prepared on the basis of FDA’s draft guidance that would allow FDA-approved patient labeling to satisfy brief summary requirements. 66 Fed. Reg. 20,468 (April 23, 2001).

<sup>3</sup> At the September 2003 DTC public meeting, CHR proposed FDA also consider permitting a standardized “Rx Facts” box or the “useful written information” that accompanies a dispensed prescription as alternatives to the current brief summary.

Letter to Daniel E. Troy, Esq.  
Thomas W. Abrams, R.Ph., MBA  
November 17, 2003  
Page 8

message should also include adequate provision for the patient to receive additional information. With the communication occurring within the pharmacy, vehicles such as the Newsletter can refer the patient to at least four different places for the FDA-approved patient labeling (if it exists), full product labeling or other information: (1) the pharmacist, from whom the patient has just received the communication; (2) the physician, with whom the patient already has a relationship; (3) a website address; and (4) a toll free number.

There is support for this multi-faceted approach to communication of prescription drug information. Several commentators at FDA's DTC promotion meeting in September 2003 urged FDA to recognize one recurrent shortcoming in its approach to accompanying information requirements – the belief that a single accompanying information vehicle must provide everything a consumer wants or needs to know about a prescription drug. Instead of requiring that every single print communication be accompanied by essentially all risk and effectiveness information, and trying to weigh what a particular communication vehicle may or may not omit, FDA should look at communication vehicles such as in-pharmacy newsletters as part of a greater whole. The goal should be to make quality prescription drug information available in a variety of formats, of varying complexity, in different media, and in locations easily accessible to consumers.

The Broadcast Guidance itself recognizes what FDA's current interpretation of the accompanying information requirements for print promotion does not – every promotion does not have to be accompanied by very detailed, technical information that likely is of little to no use to the consumer. The Broadcast Guidance's "adequate provision" approach emphasizes flexibility and understandability over completeness. The ad's major statement communicates the most significant risk information in understandable language. Completeness is addressed by informing consumers they can obtain more information through other easily accessible means, including 800 numbers, website addresses, and asking doctors and pharmacists (where the consumer would have to go regardless to have the drug prescribed and dispensed).

CHR believes that a similar model for providing accompanying information – one that emphasizes flexibility and utility to patients – is appropriate for in-pharmacy DTP communications as well. Such an approach would be very beneficial to fostering and improving in-pharmacy DTP communications such as the Newsletter. Space now devoted to recitation of lengthy and technical accompanying information could be devoted instead to useful and relevant information for the patient. We note also that in the case of providing accompanying information for a drug other than the one dispensed, including the full brief summary or even a shortened, modified form of the brief summary could prove confusing to the patient who is receiving this information at the same time he or she receives a prescription for a *different* medication. For this reason, reliance on the principles applicable to broadcast makes the most sense for in-pharmacy DTP communications.

### Conclusion

We urge FDA to consider the special nature of in-pharmacy DTP communications and in particular those involving compliance/adherence messages for the drug being dispensed. These are

Letter to Daniel E. Troy, Esq.  
Thomas W. Abrams, R.Ph., MBA  
November 17, 2003  
Page 9

useful, meaningful educational communications that augment the pharmacist/patient dialogue. FDA should be interested in encouraging these communications, not stifling them under burdensome accompanying information requirements. The different role in-pharmacy communications play, and the circumstances under which patients receive them warrant different treatment than what is applicable to other, conventional DTC print promotions.

In particular, in the forthcoming draft guidance, FDA should provide that:

- In-pharmacy DTP communications, and compliance/adherence messages in particular, do not trigger accompanying information requirements at all.
- If FDA determines otherwise, FDA should recognize that compliance/adherence messages that accompany the drug dispensed satisfy accompanying information requirements if they include the "useful written information."
- With respect to adjunctive/awareness/ alternative therapy messages in in-pharmacy DTP communications, FDA should seriously consider application of the broadcast guidance principles. Alternatively FDA should allow alternatives such as Rx Facts (a proposal CHR presented at the DTC hearing) or the "useful written information" format to be used in the pharmacy and evaluated as to their effectiveness.

CHR applauds FDA for proceeding to update and improve its accompanying information requirements for print promotion.

Respectfully submitted,



Richard L. Frank  
John W. Bode  
Counsel to Catalina Health Resource

RLF/JWB:zkf

Attachments

cc: Commissioner Mark B. McClellan, M.D., Ph.D.  
Docket No. 2003N-0344  
Ellen Shapiro, Director, Division of Public Affairs, CDER