DTC Promotion and Guidance: OPDP Update

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DTC Promotion and Guidance

- Guidance Update
- Submission Totals
- DTC Enforcement
- Tips on How to Submit to OPDP
Recent OPDP Draft Guidances

- **DTC Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program**
- **Responding to Unsolicited Requests for Off-label Information About Prescription Drugs and Medical Devices**
FDAAA DTC TV Ad Pre-Dissemination Review Guidance

• The Food and Drug Administration Amendments Act of 2007 (FDAAA) gives FDA the authority to “... require the submission of any television advertisement for a drug ... not later than 45 days before dissemination of the television advertisement”
FDAAA DTC TV Ad Pre-Dissemination Review Guidance

• In conducting the review, FDA may make recommendations on:
  
  – changes that are necessary to protect the consumer good and well-being, or that are consistent with the PI.

  – statements for inclusion in the ad to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities, if appropriate and if such information exists.
FDAAA DTC TV Ad Pre-Dissemination Review Guidance

• Describes how FDA plans to implement the requirement for the pre-dissemination review of DTC TV ads, including:
  - Types of TV ads that FDA intends to be subject to review (Six Categories)
  - How FDA will notify sponsors that an ad is subject to review
  - Procedures sponsors should follow to submit their TV ads to FDA for review.
Categories of TV ads

• **Category #1**: The initial TV ad for any prescription drug or the initial TV ad for a new or expanded approved indication for any prescription drug

• **Category #2**: All TV ads for prescription drugs subject to a REMS with elements to assure safe use

• **Category #3**: All TV ads for Schedule II controlled substances
Categories of TV ads

- **Category #4**: The first TV ad for a prescription drug following a safety labeling update that affects the Boxed Warning, Contraindications, or Warnings & Precautions section of PI.

- **Category #5**: The first TV ad for a drug following an enforcement letter (i.e., a Warning or untitled letter) that either cites a TV ad or causes a TV ad to be discontinued.

- **Category #6**: Any TV ad deemed necessary by FDA to review from a public health perspective.
Notification of Requirement to Submit

• FDA intends to notify sponsors who are subject to the pre-dissemination review requirement in one of two ways:

  - Via **Letter**: New and expanded indications (cat. 1), safety update (cat. 4), following enforcement letter (cat. 5), and otherwise identified (cat. 6)

  - Via **Federal Register Notice**: For drugs already approved that have not yet run TV ads (cat. 1), REMS with elements to assure safe use (cat. 2), and schedule II controlled substances (cat. 3)
Content and Procedures

• The content of pre-dissemination review packages and the procedures for submitting are similar to OPDP’s current voluntary TV ad advisory comment review process.
  – However, OPDP will be requesting a final recorded version of TV ad in it’s entirety.
FDAAA DTC TV Ad Pre-Dissemination Review Guidance

• In identifying categories, OPDP took a risk-based approach.
  – Approximately 25% of all TV ads submitted per year would fall under guidance criteria.

• NOTE: FDA is not implementing guidance until it is finalized.
Guidance Process for Social Media

• Research on multiple guidance topics:
  – Responding to unsolicited requests for off-label information
  – Fulfilling regulatory requirements when using tools associated with space limitations
  – Fulfilling post-marketing submission requirements
  – Online communications for which manufacturers, packers, or distributors are accountable
  – Use of links on the Internet
  – Correcting misinformation on third party websites
Draft Guidance #1

• Responding to Unsolicited Requests for Off-label Information About Prescription Drugs and Medical Devices
  – Issued December 2011 by CDER, CBER, CVM, and CDRH
  – Updates and clarifies FDA’s policies on unsolicited requests for off-label information, including those that firms may encounter through emerging electronic media
Definitions of Unsolicited Requests

• Unsolicited requests
  – Initiated by persons or entities completely independent of the relevant firm
  – Not prompted in any way by a manufacturer or its representatives

• Non-public unsolicited request
  – An unsolicited request that is directed privately to a firm using a one-on-one communication approach

• Public unsolicited request
  – An unsolicited request made in a public forum, whether directed to a firm specifically or to a forum at large
Definition of Solicited Requests

• Solicited requests
  - Requests for off-label information that are prompted in any way by a manufacturer or its representatives
  - May be considered evidence of a firm’s intent that a drug or medical device be used for a use other than that specifically approved or cleared by FDA
Solicited Request Example

- If a firm sets up a website that enables viewers to read prepared standard responses for the firm’s products that are generated from prefixed pull-down menus naming various disease states, including any standard responses related to off-label uses for the firm’s product, resulting requests for off-label information would be considered solicited.
Unsolicited Requests Draft Guidance

• Overview of FDA’s recommendations for responding to unsolicited requests for off-label information
  – Regardless of whether the initial unsolicited request for off-label information was made in a non-public or public forum, a firm that chooses to respond should provide the final response containing the requested off-label information about its product only to the specific individual who requested the information as a private, one-on-one communication
Total # of promotional pieces

*Mixed = Internet pieces, Video News Releases and “Other” Material

**Mixed pieces are listed as either professional or consumer
DTC Enforcement

• Pataday
• Atralin
• Copaxone
• Atelvia
Pataday Untitled Letter

• In October of 2011, OPDP issued an Untitled Letter to Alcon for a violative rebate card. The violations cited were:
  – Inappropriate Reminder Labeling/Omission of Indication and Risk Information
  – Unsubstantiated Superiority Claim
Instant Savings on Your PATADAY™ Solution Prescription*
Good for all prescriptions through 12/31/2011

PAY NO MORE THAN $25* with this Most Relief Rebate

*Offer restrictions: Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan or other federal or state programs (such as medical assistance programs). If you are eligible for drug benefits under any such program, you cannot use this voucher. By using this voucher, you agree that you will not submit a claim for the prescription to a government payer.

To the Patient: You must present this voucher to the pharmacist along with your prescription to participate in this program. If you have any questions regarding your eligibility or benefits, or if you wish to discontinue your participation, call the PATADAY™ Solution program at 877-264-2440 (8:00 AM-8:00 PM EST, Monday-Friday). When you use this voucher, you are certifying that you understand the program rules, regulations, and terms and conditions. You are not eligible if prescriptions are paid by any state or other federally funded programs, including, but not limited to Medicare or Medicaid, Medigap or OTC or Tricare, or where prohibited by law; and you will otherwise comply with the terms above.

- Patients are responsible for a $25 out-of-pocket expense. This instant savings voucher will then be applied toward any remaining out-of-pocket expense up to a maximum of $50.
- If you purchase PATADAY™ Solution, through mail order and they do not accept this voucher, call McKesson Corporation at 877-264-2440 and request a Direct Member Reimbursement (DMR) form.

To the Pharmacist: When you use this voucher, you are certifying that you have not submitted and will not submit a claim for reimbursement under any federal, state, or other governmental programs for this prescription.

- Submit this transaction to McKesson Corporation using BIN #610524.
- If primary coverage exists, input card information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response.
- Acceptance of this voucher and your submission of claims for the PATADAY™ Solution program are subject to the LoyaltyScript program Terms and Conditions posted at www.mckesson.com/imprint.
- Patient is not eligible if prescriptions are paid in part or full by any state or federally funded programs, including but not limited to Medicare or Medicaid, Medigap, VA, OTC or Tricare and where prohibited by law.
- For questions regarding setup, claim transmission, patient eligibility or other issues, call the LoyaltyScript for PATADAY™ Solution program at 877-264-2440 (8:00 AM-8:00 PM EST, Monday-Friday).

RxBIN: 610524
RxPCN: Loyalty
RxGRP: 50775558
ISSUER: (80840)
ID:

FOR QUESTIONS CALL 877-264-2440

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Once Daily Pataday™ (olopatadine hydrochloride ophthalmic solution) 0.2%
Pataday Untitled Letter

Inappropriate Reminder Labeling/Omission of Indication and Risk Information

- Presentation clearly indicates that Pataday is used for the relief of symptoms of allergic conjunctivitis caused by plant allergens, yet includes no indication or risk information

Unsubstantiated Superiority Claim

- “Most Relief” rebate, in conjunction with images, suggests Pataday is superior to other therapies.
In February of 2012, OPDP issued an Untitled Letter to Dow Pharmaceutical Sciences for a violative DTC website and professional detail aid. The following violation from the letter is an example of:

- Unsubstantiated Superiority/Unsubstantiated Claims
Think You’re Too Old for Acne? Think Again

Life is challenging enough without having to deal with the added stress of adult acne.

Maybe you had acne as a teen—or maybe you didn’t. The truth is, adult acne can rear its ugly head in our early to mid 20s, and stay until we’re 40 or older, for a variety of reasons. It can also stick around for years.

Adult skin has special needs

As we age, our skin loses moisture and may become drier and more sensitive. You may benefit from an acne treatment like ATRALIN™ (tretinoin) Gel 0.05% because it’s the only tretinoin that offers a unique combination of ingredients that are known to moisturize and hydrate skin.

5 reasons why ATRALIN™ Gel may be right for you

1. ATRALIN™ gel contains tretinoin—an effective ingredient for fighting acne.
2. ATRALIN™ gel contains a combination of ingredients that are known to moisturize and hydrate skin—making it more ideal for adult skin.
3. ATRALIN™ Gel has low potential for irritation. This may help you look better as your acne is getting better.
4. ATRALIN™ Gel is an elegant aqueous gel that’s designed to quickly rub in without leaving residue so it isn’t noticeable.
5. ATRALIN™ Gel is designed to help prevent future breakouts.

Important Safety Information:

- The most common adverse reactions were mild to moderate irritation of the skin and occurred during the first few weeks of treatment with ATRALIN™ Gel.
- To prevent aggravating the skin, protect it from sun, tanning lights, extreme wind or cold, and harsh skincare products.
- Use of sunscreen products of at least SPF 15 and protective clothing over treated areas is recommended when exposure cannot be avoided.
- Please see Full Prescribing Information.

*The contribution to efficacy of individual components has not been evaluated.

References:
4. Data on file, CORIA Laboratories Ltd.
Atralin Untitled Letter

• “As we age, our skin loses moisture and may be drier and more sensitive. You may benefit from an acne treatment like ATRALIN™ (tretinoin) Gel 0.05% because it’s the only tretinoin that offers a unique combination of ingredients that are known to moisturize and hydrate skin.∗”

• “ATRALIN™ Gel contains a combination of ingredients that are known to moisturize and hydrate skin∗ -making it more ideal for adult skin.”

  ∗“The contribution to efficacy of individual components has not been evaluated.”
Unsubstantiated Superiority/ Unsubstantiated Claims

• Claims suggest that Atralin is superior to other tretinoin formulations because the ingredients of Atralin’s vehicle gel provide specific clinical benefits, such as moisturizing and hydrating skin.

• To make this claim, sponsor would need adequate and well-controlled head-to-head clinical trials in which clinical benefits of the individual vehicle ingredients, including improved tolerability or efficacy, were demonstrated.
Copaxone Warning Letter

• In March of 2012, OPDP issued a Warning Letter to Teva for violative exhibit panels and DTC webpages. The following violation from the letter is an example of:
  – Overstatement of Efficacy/Broadening of Indication
“David Kyle” webpage: “Running, Swimming and Biking Against Multiple Sclerosis”

Before Copaxone

• “It’s hard to believe that just a few years ago, this energetic and dynamic athlete had to use a cane for mobility and often could barely muster enough energy to work half a day. This was the case for David, who was diagnosed with multiple sclerosis (MS) in 2002. David awoke one morning experiencing numbness in his toes.”

• “Over the course of a few weeks, the numbness moved up his body and he eventually became partially paralyzed from the chest down. The symptoms subsided briefly only to return just six months later, this time advancing to his entire right side.”
Copaxone Warning Letter

After Copaxone

- “With the help of his doctor, David began COPAXONE® (glatiramer acetate injection) therapy in 2003”

- “After a year and a half of hard work and determination, David was the USA Triathlon National Champion in the physically challenged category.”

- David went on to compete and win numerous national and international triathlons from 2005-2008.
Copaxone Warning Letter

Overstatement of Efficacy/Broadening of Indication

• Claims imply that Copaxone reverses patients’ disability and enables them to lead an active lifestyle, return to work, and/or accomplish great athletic feats.

• Broadens indication by implying that Copaxone is approved to treat all types of MS.

• Start date of therapy (2003) implies effectiveness beyond three years of data included in the PI.
Atelvia Untitled Letter

• In May of 2011, OPDP issued an Untitled Letter to Warner Chilcott for a violative video posted on YouTube. This enforcement was the result of a Bad Ad complaint. The violations cited were:
  – Omission of Risk/Indication
  – Omission of Material Facts/ Misleading Claims Regarding Dosing
  – Failure to submit on form FDA-2253
Background from Dosage and Administration section of PI:

“Atelvia should be taken in the morning immediately following breakfast. When compared with immediate-release risedronate, treatment with Atelvia resulted in a significantly higher incidence of abdominal pain when administered before breakfast under fasting conditions. Atelvia should be taken immediately following breakfast and not under fasting conditions.

To facilitate delivery to the stomach, Atelvia should be swallowed whole while the patient is in an upright position and with at least 4 ounces of plain water. Tablets should not be chewed, cut, or crushed. Patients should not lie down for 30 minutes after taking the medication.”
Atelvia Untitled Letter

• Omits risk and indication for Atelvia
• Video makes benefit claims regarding dosing, however:
  – fails to disclose material facts about dosing
  – implies that patients have a choice to eat or drink when taking Atelvia (i.e. “can eat and drink in the morning”)
Tips for How to Submit to OPDP

• Address:
  Food and Drug Administration
  Center for Drug Evaluation and Research
  Office of Prescription Drug Promotion
  5901-B Ammendale Road
  Beltsville, MD  20705

• Include a “OPDP” sticker or other prominent directional notation on the exterior of the package and on the cover letter itself

• Be sure your submission is “complete”
Tips for How to Submit to OPDP

- Consult OPDP’s website prior to submitting materials (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm)

- For time sensitive materials, please confirm receipt of the submission to OPDP with a phone call to the project manager or appropriate reviewer (301-796-1200)
Thank you!