STATUS OF CODEINE PRODUCTS

We have received a number of questions about the use of codeine products. In 2010, the FDA required four manufacturers of codeine products to withdraw their products from the market because the products had not been approved by the FDA. It appears that this action is a follow-up to remove any unapproved codeine products from the market. It also appears that approved codeine products will remain on the market and available. Below we have listed those products which we found on the FDA website showing active drugs. We have also attached the FDA notice from February and provided the website for an additional from January. We are sorry for the confusion about removal of all codeine products as indicated by our first notice of removals.

We have copied an FDA notice about the removal of many codeine products. The notice below is from the FDA web site http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm377688.htm

There is also an FDA explanation at https://www.federalregister.gov/articles/2014/01/10/2014-00257/unapproved-and-misbranded-oral-and-injectable-drugs-labeled-for-prescription-use-containing-codeine#h-12

Upon searching Drugs@FDA, which lists active drugs, we found these entries:

- ACETAMINOPHEN AND CODEINE PHOSPHATE (ACETAMINOPHEN; CODEINE PHOSPHATE)
- ACETAMINOPHEN AND HYDROCODONE BITARTRATE (ACETAMINOPHEN; HYDROCODONE BITARTRATE)
- ACETAMINOPHEN AND PENTAZOCINE HYDROCHLORIDE (ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE)
- ACETAMINOPHEN, ASPIRIN AND CAFFEINE (ACETAMINOPHEN; ASPIRIN; CAFFEINE)
- ACETAMINOPHEN, ASPIRIN, AND CODEINE PHOSPHATE (ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE)
- ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE (ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE)
- CODEINE SULFATE (CODEINE SULFATE)
- CODEINE, ASPIRIN, APAP FORMULA NO. 2 (ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE)
- CODEINE, ASPIRIN, APAP FORMULA NO. 3 (ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE)
- CODEINE, ASPIRIN, APAP FORMULA NO. 4 (ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE)

Guidance, Compliance & Regulatory Information

- Enforcement Activities by FDA
- Unapproved Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval

Questions & Answers: FDA’s Removal of Unapproved Prescription Drug Products Containing Codeine and Dihydrocodeine from the Market

Q1. What action is FDA taking regarding codeine single-ingredient, codeine combination, and dihydrocodeine combination products?

A1. The U.S. Food and Drug Administration (FDA) has ordered companies to stop manufacturing as of February 24, 2014 and distributing as of April 10, 2014 unapproved prescription drug products containing codeine and unapproved prescription drug products containing dihydrocodeine.
The drugs covered by this action lack the required FDA approval and are:
- single-ingredient codeine sulfate oral tablets;
- single-ingredient codeine phosphate injections;
- combination products containing codeine phosphate; and
- combination products containing dihydrocodeine bitartrate.

This action was published in the Federal Register on January 10, 2014.

Q2. What are codeine and dihydrocodeine?
A2. Codeine is an opioid primarily used to relieve pain (analgesic) or to treat coughs (antitussive). Dihydrocodeine is a chemical derivative of codeine and an opioid pain reliever that produces similar effects to codeine.

Q3. Why is FDA taking this action?
A3. FDA is taking this action as part of our continuing effort to ensure that prescription drugs marketed in the U.S. have the required FDA approval, which means that they have been found to be safe, effective, of good quality, and appropriately labeled.

Q4. When is this action going to take effect?
A4. Individuals and firms must stop manufacturing these prescription products within 45 days and stop distributing these products within 90 days. After these dates, all of these drug products must have FDA approval to be manufactured or distributed in interstate commerce.

Q5. What impact will FDA’s action have on patients who use prescription codeine and dihydrocodeine products? Are there alternatives?
A5. There will be little, if any, impact on patients. There are several FDA-approved drug products on the market that patients can take for symptom relief. There are approximately 55 prescription codeine/dihydrocodeine products with FDA approval. Patients should consult a health care professional for detailed guidance on their treatment options.

Q6. Are these prescription drug products recalled from the pharmacy?
A6. No, this is not a recall. Previously manufactured unapproved drug products affected by this action may still be found on pharmacy shelves for a short period of time (until the inventory has been depleted or until the products’ expiration date).

Q7. How can I tell the difference between FDA-approved and unapproved prescription drug products?
A7. Health care professionals and patients can use Drugs@FDA, National Drug Code (NDC) Directory, or the Orange Book to determine whether a drug is FDA-approved. Drugs@FDA contains most FDA-approved drug products.

The NDC Directory is limited to prescription drugs and insulin products. Search results from the NDC Directory include a column marked "Application Number." FDA-approved products will have an associated new drug application (NDA) or abbreviated new drug application (ANDA) number in this column. Identification of a drug product as "other" indicates that the product has not been FDA approved (unless there is a data error or the firm did not provide the product's application number).

Searches of drug products in the Orange Book will list approved products (note the application number in the "Appl No" column) by dosage form, route, and name of applicant. If the product is not in the FDA-approved list, then the results will state, "No matching records found."

- Table containing the NDC Number and Proprietary Name for the approved and marketed codeine and dihydrocodeine containing products as of November 12, 2013

Q8. Is it safe to use the unapproved prescription drug products?
A8. The safety of unapproved drugs is unknown. Approved prescription drug products have a label that has been specifically reviewed and approved by FDA, and that reflects the risks, benefits, and safe use of these drugs. This information may not be contained in the label of the unapproved prescription drug products.

The drug approval process enables FDA to evaluate the drug’s formulation, manufacturing process, and label, as well as any changes that occur after approval.

Q9. Should I keep taking my medications?
A9. Patients who have concerns about their medications should speak to their health care professionals about replacement prescriptions.

Q10. What do pharmacists do if they have this product on hand?
A10: FDA is directing this action at drug manufacturers and distributors in an effort to ensure that these unapproved drugs are removed from the market. FDA strongly encourages pharmacists who are presented with prescriptions for unapproved codeine products to contact the prescriber and suggest an FDA-approved prescription product.

Q11. What if I have further questions about these products?
A11. If you have further questions regarding this action, please contact the Division of Drug Information at: 888-INFO.FDA (888-463-6332), or email at: druginfo@fda.hhs.gov

Page Last Updated: 02/04/2014
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