

**Answers:** FDA Print Advertisement Activity

Source: <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/prescription-drug-advertising>

## **PRODUCT CLAIM ADVERTISEMENTS**

### **a. INCORRECT**

- 1** The image of the young girl in the ad is misleading because the fictional drug is approved for use only in adults 18 years of age and older.



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**2** Although claims generally must be supported by data from well-designed studies, consumers may not know if such studies exist or what they show. If FDA determines that claims are not supported, it will take action to have the ad fixed. In the short term, if you have doubts about a claim in an advertisement, you should talk to your healthcare provider.



**2** Makes breathing easier  
... immediately

**3** This ad falsely states that Arbitraer is approved to help control asthma symptoms. This fictional drug (see the [Correct Product Claim Ad](#)) is approved to treat seasonal nasal allergy symptoms.



**3** **Arbitraer** will help  
control your asthma symptoms

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**4** As stated above, although claims generally must be supported by data from well-designed studies, consumers may not know if such studies exist or what they show. If FDA determines that claims are not supported, it will take action to have the ad fixed. In the short term, if you have doubts about a claim in an advertisement, you should talk to your healthcare provider.



**5** This ad presents Arbitraer's risks in small type size and positions this information far from where the benefits are discussed, so it is harder for the reader to notice and read the risks. "[Fair balance](#)" requires that risks and benefits be similarly clear.



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6

The ad does not include the

"[brief summary](#),"

which includes additional required risk information.

The law requires that ads include this "brief summary."

Also, the ad does not include the statement "You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [MedWatch](#) or call 1-800-FDA-1088."

This statement is required to be included in print ads by the Food and Drug Amendments Act of 2007.

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**1 Arbitraer**  
(misvastatium) 100mg tablets

**2 Help Relieve Seasonal Allergy Symptoms**

**3** Arbitraer is a prescription medicine that helps control seasonal allergy symptoms, like runny nose, sneezing, and itchy, watery eyes. By taking Arbitraer, **once a day** you can relieve your allergy symptoms for up to 24 hours.

**4** You may begin to experience relief of allergy symptoms 2 hours after taking Arbitraer.

You may experience headaches, cold symptoms, coughing, or backaches while using Arbitraer.

**5** Arbitraer is for use in adults 18 and older. Arbitraer is not for use in children.

**6** You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1800 FDA-1088

**7** [See reverse for important information about Arbitraer.](#)

**8** Ask your doctor if **Arbitraer** is right for you.

**9** **ACE** Pharmaceuticals  
800-555-5555 [www.arbitraer.com](http://www.arbitraer.com)

This advertisement is entirely fictional—no connection between "Arbitraer (misvastatium)" and any real company or product is intended, expressed, or implied.

b. **CORRECT**

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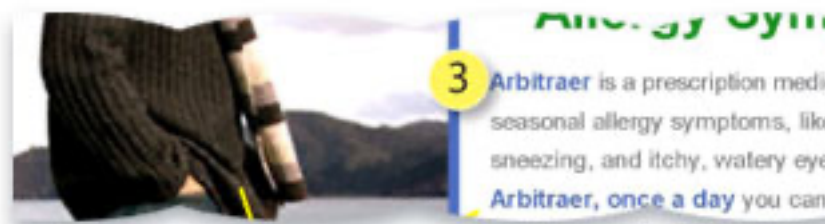
**1** Product claim ads must identify the drug's **brand** and **generic** names. The ad correctly mentions the fictional drug's brand name, Arbitraer, and its generic name, misvastatium.



**2** Product claim ads must accurately state an FDA-approved use for the drug. In addition, the ad may not make a claim that is not supported by substantial evidence or substantial clinical experience. This ad appropriately states that Arbitraer is approved to treat seasonal allergy symptoms.



**3** Product claim ads should say that the drug is given by prescription only. This ad appropriately states that Arbitraer is a prescription drug.

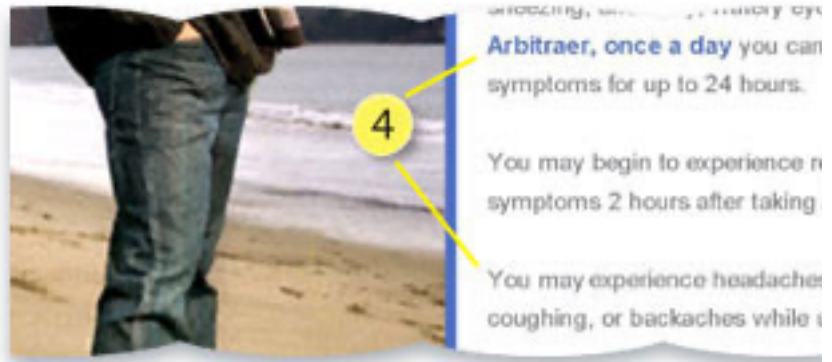




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- 4 This ad provides the required "fair balance" of information about the risks and benefits of Arbitraer. The ad as a whole does not put more emphasis on the drug's benefits than its risks.



- 5 The man on the beach who is pictured in the ad is in the approved age range for users of the drug. The ad also reinforces this point by stating that Arbitraer is for adults 18 and older and is not for use in children.



- 6 As required by the Food and Drug Amendments Act of 2007, print ads must include the statement "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [MedWatch](https://www.fda.gov/medwatch), or call 1-800-FDA-1088."



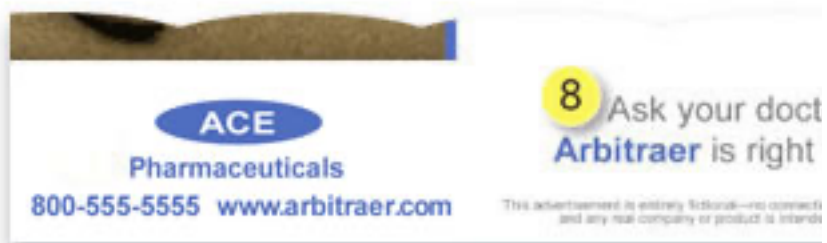
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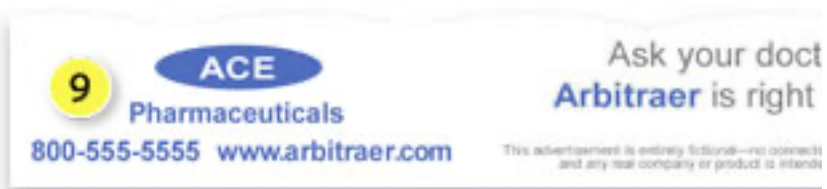
- 7 Print ads must include a "brief summary" of all the risks listed in the drug's FDA-approved prescribing information. The "brief summary" contains one or more pages of important information about a drug's risks. The "brief summary" usually follows the part of the ad that displays colorful images and graphics.  
[View the Brief Summary](#) (23Kb)



- 8 The ad directs the reader to seek a doctor's advice about taking Arbitraer. The drug company has included this statement as a way to ensure that a consumer will not think he or she is qualified to make the prescribing decision.



- 9 Product claim ads may provide sources of further information, such as a website and toll-free telephone number.

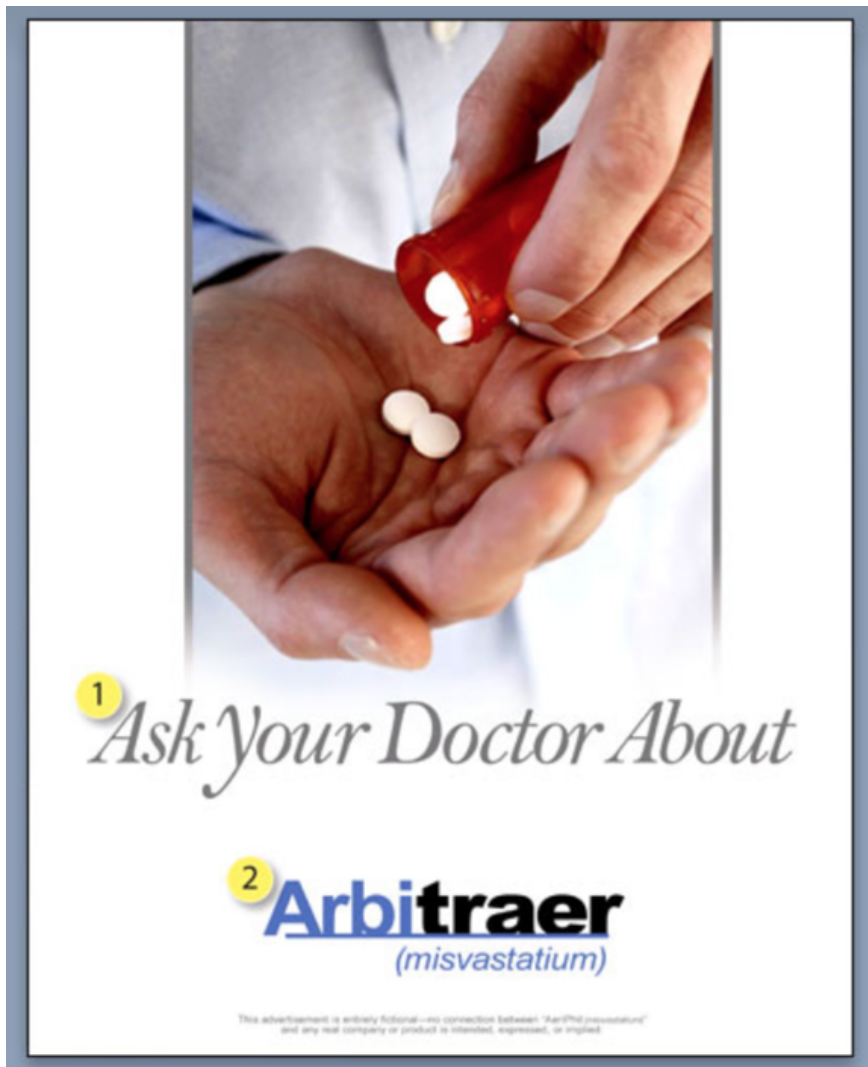




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## **REMINDER ADVERTISEMENTS**



a. **CORRECT**

- 1 The ad does not describe or name the condition the drug treats or make dosage recommendations. Notice that neither allergies nor any allergy symptoms are mentioned or pictured.



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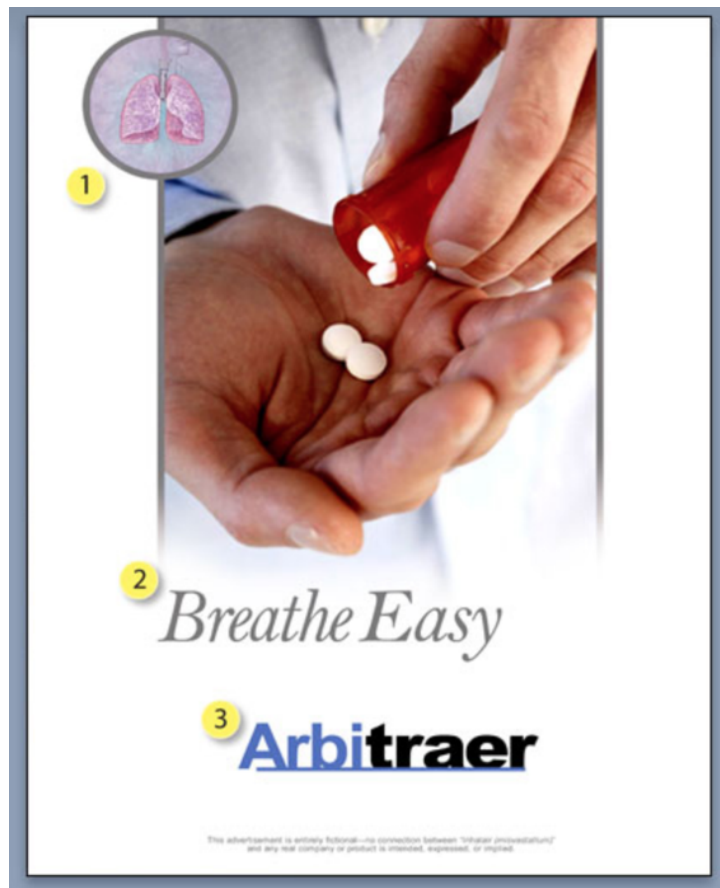
**2** Reminder ads must identify the drug's [brand name](#) (if it has one) and its [generic name](#). The ad correctly mentions the fictional drug's brand name, Arbitraer, and its generic name, misvastatium.

**2** **Arbitraer**  
(misvastatium)

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b. **INCORRECT**

1 The picture of a set of lungs suggests that the drug works on someone's lungs or on their breathing. This picture is not allowed in a reminder ad because these ads cannot suggest



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what the  
drug does.

**2** The phrase "Breathe Easy" suggests the drug will help a person breathe easier. This kind of statement is not allowed in a reminder ad because it suggests the condition the drug treats. Reminder ads must not say or suggest any benefit of the drug, or such things as who should take it.



**3** All reminder ads must mention the drug's [brand name](#) (if it has one) and [generic name](#). While this ad includes the fictional drug's brand name,



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Arbitraer, it  
incorrectly  
omits its  
generic  
name,  
misvastatiu  
m.

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## Help-Seeking Advertisements

Runny Nose?  
Sneezing?  
Itchy, Watery  
eyes?

1 You may be suffering from  
*Seasonal Allergies*

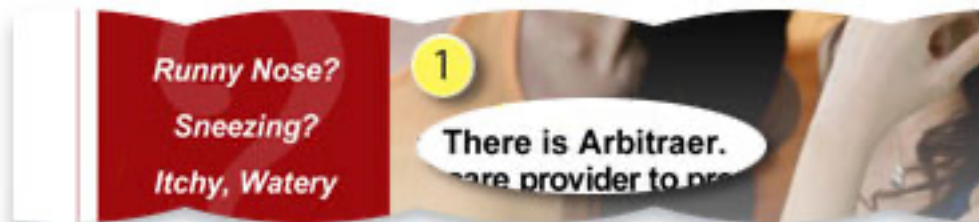
2 There is help. There is Arbitraer.  
Ask your healthcare provider to prescribe Arbitraer.

3 drug.co 800-555-5555

This advertisement is entirely fictional—no connection between "Arbitraer" and any real company or product is intended, expressed, or implied.

a. INCORRECT

- 1 The ad describes the symptoms of seasonal allergies, but it also includes the name of a specific (fictional) drug ("Arbitraer"). Therefore,





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we would  
consider it  
a product  
claim ad.  
As a result,  
the ad  
needs to  
meet all the  
requirements  
for a  
product  
claim ad.

**2** To be a  
help-  
seeking ad,  
the text  
cannot  
recommend  
a specific  
drug as a  
treatment.  
Because it  
directs the  
reader to  
ask about a  
specific  
drug, we  
would  
consider  
the ad a  
product  
claim ad.  
Directing  
the reader  
to ask a  
healthcare  
provider  
about  
symptoms  
is  
appropriate  
. To be a  
help-  
seeking ad,  
it could say,  
"Ask your  
healthcare

**2** There is help. There is Arbitraer.  
Ask your healthcare provider to prescribe Artbitraer.

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provider  
what you  
can do."

**3**

Help-seeking ads may identify the company sponsoring the ad and provide a telephone number to call or a website to visit for more information.

**3**

drug co. 800-555-5555

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1

2

Runny Nose?  
Sneezing?  
Itchy, Watery  
eyes?

You may be suffering from  
*Seasonal Allergies*

3 There is help.  
Ask your healthcare provider for more information.

4

drug co.

This advertisement is entirely fictional; no connection between "Arbitrator" (generic name) and any real company or product is intended, expressed, or implied.

c. **CORRECT**

- 1 The image in this ad identifies a person who may have seasonal allergy symptoms. The ad does not show an image of a specific drug.



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- 2** This help-seeking ad identifies seasonal allergy symptoms without identifying a possible drug treatment.



- 3** This and any help-seeking ad may recommend that readers seek the advice of their healthcare provider.



- 4** While this ad may not name a drug, it may identify the company sponsoring the ad and provide a telephone number to call or a website to visit for more information.



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