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FDA News

FOR IMMEDIATE RELEASE

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FDA Acts to Protect Public from Fraudulent Avian Flu Therapies

The U.S. Food and Drug Administration (FDA) issued warning letters recently to nine companies marketing bogus flu products behind claims that their products could be effective against preventing the avian flu or other forms of influenza. FDA is not aware of any scientific evidence that demonstrates the safety or effectiveness of these products for treating or preventing avian flu and the agency is concerned that the use of these products could harm consumers or interfere with conventional treatments.

"There are initiatives in place to deter counterfeiters and those who sell fraudulent or phony products to prevent or treat avian flu," said Andrew von Eschenbach, MD, Acting FDA Commissioner. "The use of unproven flu cures and treatments increases the risk of catching and spreading the flu rather than lessening it because people assume they are protected and safe and they aren't. I consider it a public health hazard when people are lured into using bogus treatments based on deceptive or fraudulent medical claims."

FDA issued Warning Letters to nine firms marketing products making unproven claims that they treat or prevent avian flu or other forms of influenza. Eight of the products purported to be dietary supplements. Examples of the unproven claims cited in the Warning Letters include: "prevents avian flu," "a natural virus shield," "kills the virus," and "treats the avian flu." These alternative therapies are promoted as "natural" or "safer" treatments that can be used in place of an approved treatment or preventative medical product.

In the Warning Letters, FDA advises the firms that it considers their products to be drugs because they claim to treat or prevent disease. The Warning Letters further state that FDA considers these products to be "new drugs" that require FDA approval before marketing. The letters also note that the claims regarding avian flu are false and misleading because there is no scientific basis for concluding that the products are effective to treat or prevent avian flu. The companies have 15 days to respond to FDA.

Consumers who believe that they have seen a fraudulent product can report it to the FDA at <http://www.fda.gov/oc/buyonline/buyonlineform.htm>.

For information on helping prevent flu, see the Centers for Disease Control and Prevention <http://www.cdc.gov/flu/protect/preventing.htm>.

FDA Warning Letters:

Sacred Mountain Management Inc.

http://www.fda.gov/foi/warning_letters/g5630d.pdfhttp://www.fda.gov/foi/warning_letters/g5630d.htm

BODeSTORE.com

http://www.fda.gov/foi/warning_letters/g5632d.pdfhttp://www.fda.gov/foi/warning_letters/g5632d.htm

Melvin Williams

http://www.fda.gov/foi/warning_letters/g5634d.pdf
http://www.fda.gov/foi/warning_letters/g5634d.htm

Iceland Health Inc.

http://www.fda.gov/foi/warning_letters/g5636d.pdf
http://www.fda.gov/foi/warning_letters/g5636d.htm

PolyCil Health Inc.

http://www.fda.gov/foi/warning_letters/g5629d.pdf
http://www.fda.gov/foi/warning_letters/g5629d.htm

PRB Pharmaceuticals Inc.

http://www.fda.gov/foi/warning_letters/g5628d.pdf
http://www.fda.gov/foi/warning_letters/g5628d.htm

Chozyn, LLC

http://www.fda.gov/foi/warning_letters/g5631d.pdf
http://www.fda.gov/foi/warning_letters/g5631d.htm

Vitacost.com

http://www.fda.gov/foi/warning_letters/g5633d.pdf
http://www.fda.gov/foi/warning_letters/g5633d.htm

Healthworks 2000

http://www.fda.gov/foi/warning_letters/g5635d.pdf
http://www.fda.gov/foi/warning_letters/g5635d.htm

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