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Should Diet Pill Go Over The Counter?

Federal scientists questioned last week whether there would be any lasting benefit for fat Americans in allowing over-the-counter sales of a weight-loss pill now sold only with a prescription.

GlaxoSmithKline Consumer Healthcare seeks to sell a nonprescription version of orlistat, a drug marketed as Xenical, that overweight adults could use as a weight-loss aid. The Food and Drug Administration approved a prescription version of the fat-blocking pill made by Roche in 1999.

A joint FDA advisory committee was to vote on whether to recommend approval late Monday. The agency usually follows the recommendations of its outside panels of experts. Currently, the FDA has not approved any nonprescription weight-loss drugs for sale.

In six-month clinical trials, obese people who took orlistat lost on average 5.3 pounds to 6.2 pounds more than did those who were given dummy pills. Glaxo wants people to use it for only six months at a time, but as an over-the-counter item, its use could not be policed.

However, the pill's effect ends once its use is stopped, said Dr. Julie Golden, a medical officer in the FDA's division of metabolism and endocrinology products. A previous study showed a progressive weight gain in patients after they discontinued use of orlistat, Golden said.

"I am concerned that this, while in the short term may be useful, in the long term it may not be," said FDA panel member Dr. Neal Benowitz.

Glaxo said the drug helps the overweight slim down only when combined with a diet and exercise regimen. The drug's actual effect on weight loss is "gradual and modest," said Steve Burton, Glaxo's vice president of

weight control.

"There is no magic pill for weight loss and orlistat is not a magic pill. Orlistat is a tool that will help people control their calorie intake and modify their diet," said John Dent, the pharmaceutical company's senior vice president of research and development.

Dr. Sidney Wolfe of the watchdog group Public Citizen urged the panel to reject the company's application, calling it a "desperate attempt to revive this barely effective drug by an OTC switch."

Deborah Fisher, a nurse from the Baltimore area, told the panel: "We need this new solution to losing weight and keeping it off."

"Eat less, move more: It sounds pretty simple, doesn't it? Well, as my kids say, not!" said Fisher, adding that she's dieted for 45 of her 52 years.

The proposed over-the-counter orlistat pill, called Alli (pronounced "ally"), would contain half the dose of the prescription capsule.

Alli could cost consumers \$12 to \$25 a week, Glaxo said. The company estimated 5 million to 6 million Americans a year would buy the drug if offered over the counter. Those numbers could mean at least \$1.5 billion a year in retail sales.

On Monday, FDA panel members questioned whether consumers would be able to distinguish Alli from non-approved dietary supplements also sold as weight-loss aids.

They also expressed concern about its effect on vitamin intake. Half of the patients enrolled in trials of the drug failed to under-

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January 31-February 2, 2006

Harvest Blend Regular

- Cucumber
- Carrots
- White Mushrooms
- Sweet Onions
- Green Chard
- Cilantro
- Spinach
- Red Leaf Lettuce
- Baby Bok Choy
- Jonagold Apples
- Bartlett Pears
- Bananas
- Hamlin Oranges
- Kent Mango

See the web site for details on our other options. Produce bag contents are subject to change based on availability.

OO News

We'll send out an email regarding some of these items soon, but as a special bonus for those of you who actually read the newsletter, you get to find out about these shocking items first. (Everyone now: *Whoooooo!*)

First, we now take Discover card. If you would like to switch your credit card billing over to Discover, call us and we will get that set up for you.

Second, we're continuing to have troubles with our dairy supplier not being able to provide us with the items we've ordered, which makes it difficult for us to fulfill your orders. We hope to figure out a solution soon. In the meantime, unfortunately, whole chickens are unavailable.

Finally, we'll likely be making some minor route changes in late February, mostly in the northwest and southeastern parts of town. Only a few of you will actually switch delivery days, but some of you may start receiving your produce at different times. We'll let you know when this will start!

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stand labeling directions that they should take supplemental vitamins at least two hours before or after using the pills.

The drug also could cause problems for organ transplant patients taking the drug cyclosporine as well as those on warfarin, a blood thinner. The drug's label would warn such patients against taking the weight-loss pill.

When taken with meals, orlistat blocks the absorption of about one-quarter of any fat consumed. That fat -- the equivalent of about 150 to 200 calories -- is passed out of the body in stools, which can be loose or oily as a result. Other side effects include gas, incontinence and oily spotting. About half of patients in trials experienced such side effects, the company said.

Furthermore, just 35 percent of diabetes patients in a study cor-

rectly stated that the drug was inappropriate for them, according to FDA documents.

Those results worried FDA reviewers, who questioned the risk of selling the drug directly to consumers "without the principal involvement of a learned intermediary," or prescribing doctor.

The reviewers also expressed concern about the increased potential for abuse or misuse of a prescription-free version of the drug, especially among bulimics or binge-eaters who could develop vitamin deficiencies due to chronic use.

The company said there was a "very low" potential for abuse, with only four published reports of bulimics using the drug. More than 22 million people worldwide have used orlistat in prescription form.

Recipes

Swiss Chard with Carrots

- 3 tbsp olive oil
- 1 clove of garlic
- 1 dried red chili
- 1 bunch Swiss Chard
- 3 carrots
- salt and pepper
- vinegar or lemon juice (optional)

Warm olive oil in the pan, with chilli and garlic; before the garlic browns remove from heat and take out the garlic. Wash chard, separate leaves from the stems and then cut the leaves into large pieces. Peel carrots, slice thinly on the diagonal, then into narrow strips.

In a large pan of boiling water, briefly cook chard stems and carrots until tender. Cook the chard leaves quickly in water and drain in a colander and then press the leaves with a wooden spoon to remove excess water. Mix all the vegetables together and season with salt and pepper. Dress with the chili and garlic oil. This can be served hot or at room temperature with the optional splash of vinegar or lemon juice

Alton's Meat Loaf

- 6 ounces garlic-flavored croutons
- 1/2 tsp ground black pepper
- 1/2 tsp cayenne pepper
- 1 tsp chili powder
- 1 tsp dried thyme
- 1/2 onion, roughly chopped
- 1 carrot, peeled and broken
- 3 whole cloves garlic
- 1/2 red bell pepper
- 18 ounces ground chuck
- 18 ounces ground sirloin
- 1 1/2 tsp kosher salt
- 1 egg

For the glaze:

- 1/2 cup ketchup
- 1 tsp ground cumin
- dash Worcestershire sauce
- dash hot pepper sauce
- 1 tbsp honey

Heat oven to 325 degrees F.

In a food processor bowl, combine croutons, black pepper, cayenne pepper, chili powder, and thyme. Pulse until the mixture is of a fine texture. Place this mixture into a large bowl. Combine the onion, carrot, garlic, and red pepper in the food processor bowl. Pulse until the mixture is finely chopped, but not pureed. Combine the vegetable mixture, ground sirloin, and ground chuck with the bread crumb mixture. Season the meat mixture with the kosher salt. Add the egg and combine thoroughly, but avoid squeezing the meat.

Pack this mixture into a 10-inch loaf pan to mold the shape of the meatloaf. Onto a parchment paper-lined baking sheet, turn the meatloaf out of the pan onto the center of the tray. Insert a temperature probe at a 45 degree angle into the top of the meatloaf. Avoid touching the bottom of the tray with the probe. Set the probe for 155 degrees.

Combine the ketchup, cumin, Worcestershire sauce, hot pepper sauce and honey. Brush the glaze onto the meatloaf after it has been cooking for about 10 minutes.

Garden Vegetable Soup

- 4 tbsp olive oil
- 2 cups chopped leeks, white part only
- 1/2 cup finely minced garlic
- Kosher salt
- 2 carrots, peeled and chopped into rounds
- 2 cups peeled and diced potatoes
- 2 cups fresh green beans, broken or cut into 3/4-inch pieces
- 2 quarts chicken or vegetable broth
- 4 cups peeled, seeded, and chopped tomatoes
- 2 ears corn, kernels removed
- 1/2 tsp freshly ground black pepper
- 1/4 cup packed, chopped fresh parsley leaves
- 1 tsp freshly squeezed lemon juice

Heat the olive oil in large, heavy-bottomed stockpot over medium-low heat. Once hot, add the leeks, garlic, and a pinch of salt and sweat until they begin to soften, approximately 7 to 8 minutes. Add the carrots, potatoes, and green beans and continue to cook for 4 to 5 more minutes, stirring occasionally.

Add the stock, increase the heat to high, and bring to a simmer. Once simmering, add the tomatoes, corn kernels, and pepper. Reduce the heat to low, cover, and cook until the vegetables are fork tender, approximately 25 to 30 minutes. Remove from heat and add the parsley and lemon juice. Season, to taste, with kosher salt. Serve immediately.