



DATE: June 26, 2014
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: Doctor's Best - RECALL [Drug]

AFFECTED PRODUCT: Red Yeast Rice dietary supplement

SUMMARY: Unclassified Recall; The recall has been initiated because the product has been found to contain undeclared lovastatin, a previously approved drug indicated for the treatment of high cholesterol, making this an unapproved new drug.

Red Yeast Rice is used as a dietary supplement for lowering cholesterol and is packaged in white plastic bottle with orange flip-top lid, 600 mg Capsules, 120-count bottles and clear tamper evident outer seal number of units, UPC code 753950001183. Red Yeast Rice product includes the following lot 3121005 and expires February 2017.

Red Yeast Rice was distributed nationwide through retail and internet outlets

SUGGESTED ACTION: For consumer inquiry only. Consumers with questions regarding this recall can contact Doctor's Best at 1-844-717-0190 Monday through Friday 9am to 5pm PDT.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Doctor's Best Issues Voluntary Nationwide Recall of Red Yeast Rice due to Undeclared Lovastatin

Contact:
Consumer:
1-844-717-0190

FOR IMMEDIATE RELEASE - June 24, 2014 - Doctor's Best is voluntarily recalling lot 3121005 (7379 bottles) of Doctor's Best Issues Voluntary Nationwide Recall of Red Yeast Rice due to Undeclared Lovastatin

Contact:
Consumer:
1-844-717-0190

FOR IMMEDIATE RELEASE - June 24, 2014 - Doctor's Best is voluntarily recalling lot 3121005 (7379 bottles) of Red Yeast Rice dietary supplement, 600 mg Capsules, 120-count bottles to the retail level. Red Yeast Rice has been found to contain undeclared lovastatin, a previously approved drug indicated for the treatment of high cholesterol, making this an unapproved new drug.

Consumers who use supplements found to contain lovastatin in rare cases could result in serious muscle injury; particularly if taking with prescription "statins" such as lovastatin, simvastatin, or atorvastatin. Pregnant women could theoretically put their unborn child at risk by using this product with undeclared lovastatin. Patients with pre-existing liver disease may be at an increase risk for liver injury following chronic use of statins.

Doctor's Best has not received any reports of adverse events related to this recall. Red Yeast Rice is used as a dietary supplement for lowering cholesterol and is packaged in white plastic bottle with orange flip-top lid, and clear tamper evident outer seal number of units, UPC code 753950001183. Red Yeast Rice product includes the following lot 3121005 and expires February 2017.

Red Yeast Rice was distributed nationwide through retail and internet outlets. Doctor's Best is notifying its distributors and customers by mail and is arranging for return of all recalled products. Consumers/distributors/retailers that have Red Yeast Rice which is being recalled should discontinue usage and return the unused portion to their place of purchase.

Consumers with questions regarding this recall can contact Doctor's Best at 1-844-717-0190 Monday through Friday 9am to 5pm PDT and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is voluntary and is being conducted with the knowledge of the U.S. Food and Drug Administration.

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Photos**

