

# Budget cuts FDA safety checks

## Calls for fewer visits to inspect food, medicine

By Julie Appleby | Feb 15, 2005 | 424 words, 0 images

The Food and Drug Administration's proposed budget for next year includes cuts to nearly all its inspection programs, from checks on imported food to reviews of overseas plants that make prescription drugs bound for the USA.

If Congress approves, the number of domestic food safety inspections made next year would fall by 5%, foreign drug plant inspections would drop 5.8% and checks on the nation's blood banks would be cut 4.7%, compared with estimated 2005 inspections.

The reductions are included in a \$1.9 billion budget that gives the agency an overall 4.5% increase. Increases are earmarked for several projects, including expansion of a network of labs to analyze food for bioterror agents and increasing staffing in the office that monitors the safety of prescription drugs once they hit the market.

The proposed cuts come amid criticism the FDA failed to inspect often enough a long-troubled British vaccine plant that the United States had counted on for half of its flu vaccine supply. All the plant's vaccine was impounded last year after British regulators discovered serious problems, which were later confirmed by the FDA.

Some experts fear reducing inspections could make the USA more vulnerable to counterfeit drugs or improperly made products.

"We don't want to end up with a buyer-beware market for necessary medicines," says Sarah Sellers, an FDA adviser, pharmacist and drug-safety expert.

In a statement, the FDA said it is targeting inspections where risks are highest: "Intelligent, risk-based inspections are more important than absolute numbers of inspections. (The agency) is committed to carrying out our mandate of promoting and protecting the public health."

Responding to ongoing criticism of the FDA's role in the vaccine problems this year, a top FDA official last week told Congress the agency will begin inspecting vaccine plants once a year, rather than the once every two years that is required.

Still, the number of drug plant manufacturing inspections would drop from 1,430 this year to 1,355 next year. The number of foreign drug inspections would fall from 515 to

485. The FDA also inspects companies that process human tissue for medical uses and companies that produce cheese, fish, juice and other foods.

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**FDA cuts inspections**

Estimated percentage reductions from 2005 to 2006 in inspections of:

Food safety 5.0%

Fish 5.1%

Drug processing 5.2%

Blood banks 4.7%

Total FDA and state contract inspections 2.4%

Total FDA and state partnership drug inspections 5.2%

Total FDA foreign drug inspections 5.8%

Source: FDA

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