

FDA: tobacco companies must report chemicals

March 30 2012, By MATTHEW PERRONE, AP Health Writer

(AP) -- Tobacco companies will be required to report the levels of dangerous chemicals found in cigarettes, chew and other products under the latest rules designed to tighten regulation of the tobacco industry.

The preliminary guidance issued Friday by the Food and Drug Administration marks the first time tobacco makers will be required to report quantities of 20 chemicals associated with cancer, lung disease and other health problems. The FDA will require companies to display the information in a consumer-friendly format by next April.

Constituents or byproducts of tobacco products that are subject to the new rule include ammonia, carbon monoxide and formaldehyde.

Regulators have identified more than 93 harmful or potentially harmful chemicals in tobacco products, though the agency is only focusing on 20 for the coming year. The agency will take comments on the guidance until June 4, before finalizing them.

A law enacted in 2009 gave the FDA authority to regulate a number of aspects of tobacco marketing and manufacturing, though the agency cannot ban nicotine. The same law lets the agency approve ones that could be marketed as safer than what's currently for sale.

In separate guidance issued Friday, the FDA laid out the scientific studies it will require before any company can market a so-called modified-risk tobacco product. Companies must submit extensive testing



data on health risks, user behavior and consumer understanding of marketing materials for new products.

"The law sets a high standard to make sure that tobacco products marketed to reduce risk actually reduce risk," Dr. Lawrence Deyton, director of FDA's tobacco center, told reporters on a conference call.

The FDA's handling of modified-risk products has been highly anticipated by both the public health community and bigger tobacco companies, which are looking for new products to sell as they face declining cigarette demand due to tax increases, health concerns, smoking bans and social stigma.

Some tobacco companies have alternatives like snus - small pouches like tea bags that users stick between the cheek and gum - and dissolving tobacco - finely milled tobacco shaped into orbs, sticks and strips. But they are not explicitly marketed as less risky than cigarettes.

Industry experts expect it will take the FDA a year or more to review applications for modified risk products.

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