FDA Opens Public Docket for Tobacco Product Good Manufacturing Practices

The Food and Drug Administration published a proposed rule announcing the availability of a public docket to receive input on recommendations for regulations on good manufacturing practice for tobacco products. The 2009 Family Smoking Prevention and Tobacco Control Act gave FDA authority to regulate tobacco product manufacturing practices for the protection of public health. Specifically, FDA is permitted to “prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology.” In response to this, a group of 13 tobacco companies submitted to FDA recommendations for good manufacturing practice regulations, on which the Agency is now seeking comment. “FDA is establishing this docket to provide an opportunity for all interested parties to comment on the tobacco companies’ recommendations and to share information that will improve FDA’s understanding of the tobacco industry and its manufacturing operations.” Comments are due on May 20th.

In the News

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- Insurers warn of sticker shock due to health care law’s taxes, requirements as it expands, Washington Post
- Lawsuit charges Ed Department with violating student privacy rights, Washington Post
- Career official takes over as Obama’s acting regulatory czar, The Hill
- Treasury Official Defends Risk Council Approach on Transparency, Bloomberg
- Paul Volcker on Banking Regulations, Fed Policy, Bloomberg TV

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- Should Insurance Regulators Handle Derivatives?, Bloomberg TV
- Stress Tests-Banker Pay, Google, FX Debates: Compliance, Bloomberg
- Improved Truck Trailers Still Capable of Killing Drivers, Bloomberg
- No spin: Regulators eye new rules for ceiling fans, The Hill
- Don’t expect quick action on painkillers, FDA tells lawmakers, The Hill
- Senate probe finds JPMorgan hid losses, risks of trading operation that lost $6.2B, Washington Post
- Government watchdog under fire for allegedly backing corporate interests, Washington Post
- Senator accuses EPA of using ‘secret data’ to write regulations, The Hill
- New community bankers leader vows fight against onerous regs, The Hill
- Consumer bureau sets sights on student loan servicers, The Hill
Small-business office confronts critics: 'We do not block rules'. The Hill

Employers Blast Fees From New Health Law, Wall Street Journal

OCC Failed to Properly Investigate JPMorgan: Report, Bloomberg TV

Why Derivatives Are Still Not Regulated, Bloomberg TV

Dimon Misled Investors, Dodged Regulators: Report, Bloomberg TV

Treasury's Lew on U.S. Manufacturing, Dodd-Frank, Bloomberg TV

JPMorgan Boosts Payout More Than Expected After Fed Approval, Bloomberg

Goldman Sachs Corrected Error in Stress Test Submission to Fed, Bloomberg

Ally Financial's Capital Plan Rejected by Fed After Stress Tests, Bloomberg

U.S. lawmakers want more transparency on financial risk council, Reuters

Judge rules U.S. SEC can withhold FINRA records from the public, Reuters

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FDA weighs tobacco company proposals, The Hill

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SAC Criminal Probe May Speed Up With SEC Allegations, Bloomberg

Fed’s Fisher Says Too-Big-to-Fail Banks Should Be Shrunk, Bloomberg

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Obama to nominate Justice Department’s Thomas Perez as labor secretary, Washington Post

U.S. regulators probing high-speed traders for ‘wash trades’, Reuters

Divided Views of SAC Capital Settlement, New York Times

High-Frequency Firms’ Wash Trades Need U.S. Review, Chilton Says, Bloomberg

U.S. seeks closer oversight of student loan firms, USA Today

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Obama Chooses Perez as Labor Secretary to Replace Solis, Bloomberg

FERC Power Limited, JPM Hearings, SAC Capital: Compliance, Bloomberg

Senator places hold on EPA nominee, The Hill

Why the EPA might delay its carbon rules for new power plants, Washington Post

Biographical information for Labor Secretary nominee Thomas Perez, Washington Post

Warning alerts on quiet cars must be ‘pleasant,’ automakers tell NHTSA, Washington Post

EPA wants lawsuit by W.Va. chicken grower dismissed; farm bureaus say issues must be heard, Washington Post

New regulations limit waiting periods for employer health plans, The Hill

Coal state Dems press Obama to scale back EPA emissions rules, The Hill

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HHHS touts Obama health law’s free preventive care, The Hill

Unions hope Labor pick will spur action on worker rules, The Hill

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White Has Bipartisan Support for SEC as Panel Nears Vote, Bloomberg

SEC, consumer banking picks clear committee, Washington Times

US won’t appeal ruling blocking graphic cigarette warnings, FDA to revise labels, Washington Post

US safety regulators open probe into fuel leaks in about 250,000 E-Class Mercedes cars, Washington Post

Panel approves consumer watchdog nominee, but confirmation fight wages on, Washington Post

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Rulemaking

Department of Agriculture
USDA Finalizes Weekly Export Sales Reporting Requirements for Pork, but not Dried Grain
The Department of Agriculture published a final rule finalizing many components of USDA’s June 25, 2012 proposed rule, Export Sales Reporting Requirements, requiring weekly reporting of all export sales for pork to the Foreign Agricultural Service (FAS). “Exporters provide information on the quantity of the sale transaction, the type and class of commodity, the marketing year of shipment, the export amount, and the destination. They also report any change of previously reported information, such as cancellations and changes in destination. A weekly summary of the export sales activity is published every Thursday at 8:30 a.m. eastern time, unless a change of time is announced. The “U.S. Export Sales” report does not provide data on individual firms, only a compilation of activity by commodity. Any person (exporter) who knowingly fails to make a report could be fined up to $25,000, imprisoned for not more than one year, or both.” The proposed rule extended export sales reporting requirements to pork and dried grain to make the market more transparent, and to provide the public with the same level of information on futures markets as members of industry. However, dried grain is not being subject to reporting requirements in the final rule in response to two adverse public comments, and USDA will give this topic further review and solicit additional public input before moving forward with a reporting requirement for dried grain.

Department of Energy
DOE Initiates Rulemaking Process for Ceiling Fan Energy Efficiency Standards
The Department of Energy published a proposed rule announcing that the Department is initiating the rulemaking process for amending the energy standards applicable to ceiling fans and ceiling fan light kits. The Department has also prepared a framework document on potential new energy standards, on which it is currently seeking public comment. “This Framework Document also includes DOE’s preliminary review of relevant industry test procedures and testing methods used to characterize the performance of ceiling fans and ceiling fan light kits in all modes of operation. DOE has also included in this Framework Document a detailed summary of key issues that DOE is considering in developing its own test procedures and for use in developing energy conservation standards for ceiling fans and ceiling fan light kits. In addition, DOE has identified issues regarding the testing of ceiling fans and ceiling fan light kits on which it is seeking comment. DOE will consider the feedback received in response to this Framework Document in developing proposed test procedures for ceiling fans and ceiling fan light kits.” Comments are due on April 29th.

Consumer Product Safety Commission
CPSC Seeks Comment on Upholstered Furniture Fire Safety Technologies
The Consumer Product Safety Commission published a proposed rule announcing the Commission’s intent to hold a meeting on upholstered furniture fire safety technologies on April 25th from 9:00am – 4:00pm. “In general, the meeting will focus on current and anticipated progress on fire barrier technologies and other options to reduce the
fire hazard posed by residential furniture.” Topics being considered for discussion at the meeting are as follows: Fire Barriers, Commercial Furniture Fire Safety Technologies, and Application of Other Fire Safety Technologies to Residential Furniture. Members of the public can RSVP here.

The Commission is also seeking comments on this topic. “We request comments on the possibility of moving from a regulatory approach that primarily addresses fire deaths caused by smoldering ignition sources using bench scale models to one that relies on the use of fire barriers to address fires started by multiple types of ignition sources (including smoking materials) by limiting fire growth similar to the performance requirements in 16 CFR 1633. Staff has encountered problems with controlling standard materials (foam, fabric, barriers) when used in bench scale tests with a smoldering ignition source.” Comments are due on July 1st.

Environmental Protection Agency
EPA Finalizes Amendments to NAAQS Nitrogen Dioxide Monitoring Requirements
The Environmental Protection Agency published a final rule revising the deadlines established in the national ambient air quality standard (NAAQS) for nitrogen dioxide (NO₂) for the near-road component of the NO₂ monitoring network to implement a phased deployment approach. “This rulemaking will result in the following actions: (1) A change to the dates by which required near-road NO₂ monitors will need to be identified in state Annual Monitoring Network Plans; (2) a change to the dates by which required near-road NO₂ monitors shall be operational; and (3) a shift in the authority to approve NO₂ monitoring plans from the EPA Administrator to the EPA Regional Administrators.” This phased implementation approach is being applied in order to give states more time to establish the required near-road NO₂ monitors; “No changes are being made with regard to the implementation timing requirements for area-wide monitoring and for monitoring to characterize NO₂ exposures for susceptible and vulnerable populations.”

Federal Communications Commission
FCC Seeks Comment on Determinations of Unsubsidized Competitors
The Federal Communications Commission published a proposed rule seeking comment from the public on how best to determine which entities are unsubsidized competitors for the implementation of Connect America Phase II. “In this document, the Federal Communications Commission seeks comment on how it will determine which census blocks are served by an unsubsidized competitor, how price cap carriers will demonstrate they are meeting the Commission’s requirements for reasonable comparability, and what other providers will need to demonstrate to be deemed unsubsidized competitors.” Comments are due on March 28th.

National Credit Union Administration
NCUA Proposes Rule for Federal Credit Union Ownership of Fixed Assets
The National Credit Union Administration published a proposed rule to clarify its existing rules governing federal credit union (FCU) ownership of fixed assets. “NCUA’s fixed assets rule: (1) Limits FCU investments in fixed assets; (2) establishes occupancy, planning, and disposal requirements for acquired and abandoned premises; and (3) prohibits certain transactions. For purposes of the rule, fixed assets are premises, furniture, fixtures, and equipment, including any office, branch office, suboffice, service center, parking lot, facility, real estate where a credit union transacts or will transact business, office furnishings, office machines, computer hardware and software, automated terminals, and heating and cooling equipment.” The proposed amendments to this rule do not make any substantive changes to the regulatory requirements, but are intended to clarify existing requirements for easier comprehension and implementation. Comments are due on May 20th.

Agencies

Department of Justice
BOP Increases Cost of Incarceration Fee to $28,893.40
The Bureau of Prisons published a notice announcing the fee levied on some inmates to cover the average cost of incarceration is being increased from $28,284 to $28,893.40. This fee is enabled through 28 CFR part 505, which allows for the assessment and collection of a fee to cover the average cost of incarceration for Federal inmates. This incarceration fee applies to inmates “convicted in U.S. District Courts, committed to Bureau custody, and serving a period of incarceration which began on or after January 1, 1995.” The Bureau of Prisons annually revisits the average annual cost of incarceration, and adjusts the fee to more accurately reflect that cost.
Export-Import Bank
Ex-Im Bank Receives Application for $100+ Million to Fund Export of Mining Equipment to Mongolia
   The Export-Import Bank published a notice announcing the receipt of an application for a long-term loan or financial guarantee in excess of $100 million to fund the export of mining equipment and services to Mongolia. The exports would be used to develop and operate a copper and gold mine in Mongolia; comments are due on April 9th.

Ex-Im Bank Receives Application for $100+ Million to Fund Boeing 777 Exports to Kuwait
   The Export-Import Bank published a notice announcing the receipt of an application for a long-term loan or financial guarantee in excess of $100 million to fund the export of commercial Boeing 777 aircraft to Kuwait. The exports would be used for long-haul passenger service between Indonesia and destinations in Europe, Asia and the Middle East. Comments are due on April 12th.

Ex-Im Bank Receives Application for $100+ Million to Fund GE Turbine Exports to United Arab Emirates
   The Export-Import Bank published a notice announcing the receipt of an application for a long-term loan or financial guarantee in excess of $100 million to fund the export of General Electric (GE) turbines to the United Arab Emirates. These exports would be used to expand a power plant to support an expansion of an aluminum smelter. Comments are due on April 12th.

Ex-Im Bank Receives Application for $100+ Million to Fund Boeing 777 Exports to China
   The Export-Import Bank published a notice announcing the receipt of an application for a long-term loan or financial guarantee in excess of $100 million to fund the export of commercial Boeing 777 aircraft to China. These exports would be used to provide long-haul airline service between China and various international destinations. Comments are due on April 15th.