SEC Proposes Long-Awaited Crowdfunding Rule for Small Business, Startups

The Securities and Exchange Commission published a much-anticipated proposed rule establishing the legal framework for crowdfunding of small enterprises via the Internet. “In the United States, crowdfunding in its current form generally has not involved the offer of a share in any financial returns or profits that the fundraiser may expect to generate from business activities financed through crowdfunding. Such a profit or revenue-sharing model—sometimes referred to as the “equity model” of crowdfunding—could trigger the application of the federal securities laws because it likely would involve the offer and sale of a security.” Such an offering would require registration with the SEC, which is untenable for smaller enterprises seeking only to raise a small amount of capital through crowdfunding. “Limitations under existing regulations, including restrictions on general solicitation and general advertising and purchaser qualification requirements, have made private placement exemptions generally unavailable for crowdfunding transactions, which are intended to be made to a large number of potential investors and not limited to investors that meet specific qualifications.” Pursuant to the Jumpstart Our Business Startups Act (the “JOBS Act”), SEC is proposing to exempt from registration requirements entities seeking to raise less than $1 million in a 12-month span. Additionally, crowdfunding transactions must take place through a registered intermediary. Comments are due on February 3rd, 2014.
Occational Safety and Health Administration

OSHA Extends Comment Deadline for Long-Delayed Rule Limiting Worker Exposure to Silica

The Occupational Safety and Health Administration is extending the comment period for its long-delayed proposed rule, Occupational Exposure to Crystalline Silica, which would limit occupational exposure to respirable crystalline silica. Previous to publication, the proposal had been under review at the Office of Information and Regulatory Affairs (OIRA) for 922 days (since February 14, 2011). Crystalline silica has a wide variety of uses in industry (for example, the sand and gravel used in road building and concrete construction). At current exposure levels, “employees exposed to respirable crystalline silica face a significant risk to their health” which will be reduced by the proposed standards. “As shown, the proposed rule is estimated to prevent 688 fatalities and 1,585 silica-related illnesses annually once it is fully effective, and the estimated cost of the rule is $637 million annually. Also as shown in Table SI-1, the discounted monetized benefits of the proposed rule are estimated to be $5.3 billion annually, and the proposed rule is estimated to generate net benefits of $4.6 billion annually. These estimates are for informational purposes only and have not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for this proposed silica rule. The courts have ruled that OSHA may not use benefit-cost analysis or a criterion of maximizing net benefits as a basis for setting OSHA health standards.” Comments are now due on January 27th, 2014.

National Credit Union Administration

NCUA Proposes to Conduct Stress Testing for Federally-Insured Credit Unions Bigger than $10 Billion

The National Credit Union Administration published a proposed rule requiring federally-insured credit unions (FICUs) to prepare and submit capital plans to the NCUA annually, and proposing that NCUA conduct annual stress tests of FICUs larger than $10 billion. “The NCUA Board (Board) has determined, to protect the National Credit Union Share Insurance Fund (NCUSIF) and the credit union system, that the largest FICUs should have systems and processes to monitor and maintain their capital adequacy. This notice of proposed rulemaking (NPRM) requires FICUs with assets of $10 billion or more (covered credit unions) to submit capital plans annually to NCUA. The Board has also determined that stress testing of these larger FICUs would provide useful information for both NCUA and the FICUs.” Comments are due on December 31st.

Commodity Futures Trading Commission

CFTC Finalizes Collateral Requirements for Swap Dealers and Major Swap Participants

The Commodity Futures Trading Commission published a final rule implementing Title VII of the Dodd-Frank Act, with requirements for the treatment of collateral by swap dealers and major swap participants. “Specifically, the final rule contained herein imposes requirements on swap dealers (“SDs”) and major swap participants (“MSPs”) with respect to the treatment of collateral posted by their counterparties to margin, guarantee, or secure uncleared swaps. Additionally, the final rule includes revisions to ensure that, for purposes of subchapter IV of chapter 7 of the Bankruptcy Code, securities held in a portfolio margining account that is a futures account or a Cleared Swaps Customer Account constitute ‘customer property’; and owners of such account constitute ‘customers.’” The Commission estimates that the final rule “will require a total of approximately 162,500 disclosures per year, generating an estimated total annual information collection burden of approximately 325,000 hours and cost of $16,250,000.”

Food and Drug Administration

FDA Proposes Rule Requiring Certain Drug Manufacturers to Notify FDA of Drug Shortages

The Food and Drug Administration is proposing to amend its regulations to implement certain drug shortage provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). The proposed rule requires all manufacturers of certain drugs—including certain applicants of blood or blood components for transfusion—and all manufacturers of covered drugs marketed without an approved application to notify FDA of a permanent discontinuance or an...
interruption in manufacturing of these drugs 6 months in advance of the permanent discontinuance or interruption in manufacturing, or as soon practicable. FDASIA also requires FDA to maintain a current list of drugs that are determined by FDA to be in shortage in the United States, and to include on that public list certain information about those shortages.

Estimated total annual costs of the interactions between industry and FDA range between $14.9 million and $47.6 million. Discounting over 20 years, annual quantified benefits from avoiding the purchase of alternative products, managing product shortages, and life-years gained, would range from $27.5 million to $86.7 million using a 3 percent discount rate. The public health benefits, mostly nonquantified, include the value of information that would assist FDA, manufacturers, health care providers, and patients in evaluating, mitigating, and preventing shortages of drugs and biological products that could otherwise result in delayed patient treatment or interruption in clinical trial development. Comments are due January 3rd, 2014.

Agencies

Food and Drug Administration
FDA Releases Risk Profile for Pathogens in Imported Spices
The Food and Drug Administration released a draft risk profile entitled “FDA Draft Risk Profile: Pathogens and Filth in Spices” to respond to recent outbreaks in the United States of human illness associated with consumption of certain spices in addition to other reports in the literature and within FDA suggesting that current pathogen control measures in spices may not adequately protect public health. “The objectives of the draft risk profile are to: (1) Describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spice; (2) describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States; (3) identify potential additional mitigation and control options; and (4) identify data gaps and research needs.” The draft risk profile is intended to provide information for FDA risk managers to use in regulatory decision making related to the safety of spices in the U.S. food supply. The information may also be useful to stakeholders and interested parties such as spice producers and importers, spice and food manufacturers, retail food establishments, and consumers. Interested parties may submit comments by January 3rd, 2014.

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