I. Background

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. This NPRM describes the stress testing NCUA will conduct of covered credit unions.

The Board of Governors of the Federal Reserve System (Federal Reserve) requires large bank holding companies to submit capital plans to the Federal Reserve. The requirement supports the Federal Reserve’s expectation that large bank holding companies have robust systems and processes that incorporate forward-looking projections of revenue and losses to monitor and maintain their internal capital adequacy. The Federal Reserve, the Federal Deposit Insurance Corporation (FDIC), and the Office of the Comptroller of the Currency (OCC) have issued regulations, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), requiring their supervised institutions to conduct annual stress tests.

II. Proposed Rule

A. Credit Union Capital Planning and Analysis

The proposed rule requires covered credit unions to develop and maintain a capital plan and submit this plan to NCUA by March 31 of each year. NCUA took into account the risk to the NCUSIF of the largest FICUs as it considered the need for capital plans at these institutions. The size of these institutions relative to the NCUSIF and the credit union system, determined, to protect the National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

G. Process Overview.

The process overview describes the stress testing NCUA will conduct of the FICUs.

The proposed rule requires a covered credit union to perform specific capital analyses. At a minimum, covered credit unions must conduct a sensitivity analysis to evaluate the effect on capital of changes in variables, parameters, and inputs used by the credit union in its capital plans. Credit unions must also test the impact of interest rate shocks of at least ± 300 basis points on the net economic value of the credit union, using final maturities of non-maturity shares not exceeding two years. Covered credit unions must also analyze the impact of credit risk to capital under unfavorable conditions, both separately and in combination with unfavorable interest rate scenarios.

B. Applicability

The proposed rule would apply to all FICUs that report $10 billion or more in assets on their March 31 Call Report. For example, if a FICU reports $10 billion or more in assets on March 31, 2014, it would be required to evaluate its capital under unfavorable conditions and submit a capital plan by March 31,
2015. The specific details of the required capital plan and accompanying capital analysis are discussed below.

C. Governance of Capital Planning and Analysis

To emphasize the importance of credit union board oversight of the capital planning and analysis process, the proposed rule provides that a covered credit union’s board of directors is expected to understand and approve processes that are consistent with the financial condition, size, complexity, risk profile, scope of operations, and level of regulatory capital of the credit union.

Senior management with responsibility for accomplishing these critical objectives must take into account all of the complexities of the credit union’s risk exposures and operations. The capital planning process should reflect the risk management of the credit union, and senior management responsible for establishing and maintaining the capital planning functions should report directly to the board of directors.

The capital analysis policy approved by the covered credit union’s board should be established and reviewed in conjunction with the credit union’s capital plan. NCUA will consider these together in assessing the safety and soundness of a credit union.

D. NCUA Action on Capital Plans

Under the proposed rule, NCUA will notify a covered credit union of the agency’s acceptance or rejection of the capital plan by June 30 of the year it is submitted. NCUA may reject the plan if there are material unresolved supervisory issues associated with the planning process. NCUA may also reject the plan if the assumptions, methodologies, or analysis underlying the plan are not reasonable or appropriate or if the data used lacks integrity or is not sufficiently detailed. In the event NCUA objects to the credit union’s capital plan, the credit union must update and re-submit a plan within 30 days of receiving notice of the objection. The plan must address deficiencies identified by NCUA and remediation for any unresolved supervisory issues which have been identified as contributing to the rejection of the plan.

Any covered credit union operating without an NCUA-approved capital plan after September 30 of the year in which the plan was submitted will be subject to supervisory actions on the part of NCUA. Before taking any action on the capital plan of a federally insured, state-chartered credit union, NCUA will consult with the applicable state supervisory authority.

E. Annual Supervisory Stress Testing

NCUA will conduct independent stress tests on all covered credit unions based on September 30 financial data. These stress tests are for the agency to independently conduct forward-looking assessments of risk vulnerabilities and stress test capital positions in the credit unions. NCUA will provide a description of the baseline, adverse, and severely adverse scenarios underlying the test by December 1 of the same year. The scenarios will be based on those developed by the Federal Reserve, the FDIC, and the OCC for their regulated institutions, although there may be variations based on credit union-specific factors. If NCUA’s stress test shows that a covered credit union does not have the ability to maintain a stress test capital ratio of at least 5 percent on a pro-forma basis under expected and stressed conditions throughout the quarter stress test period, NCUA will require the credit union to take steps to enhance capital and/or may take other supervisory action against the credit union.

In arriving at a minimum stress test capital ratio of 5 percent, NCUA considered minimum net worth ratio requirements under the Prompt Corrective Action regulation. NCUA considers a credit union to be significantly undercapitalized when its net worth ratio is between 2 percent and 3.99 percent, and critically undercapitalized when its ratio is less than 2 percent. A minimum stress test capital ratio requirement is intended to provide prospective information of credit union capital adequacy. NCUA believes that a minimum ratio of 5 percent allows for a credit union to take corrective measures before it becomes significantly or critically undercapitalized. Under these latter two classifications, the credit union’s operating environment would be influenced by mandatory, discretionary, and other supervisory actions, enhanced public scrutiny and member concern over the safety of its deposits leading to abnormal withdrawals. These pressures may limit the credit union’s ability to restore confidence and its financial soundness in a timely manner, thus jeopardizing future viability.

In establishing a 5 percent ratio, NCUA also considered the minimum leverage ratio for banks, which is now 4 percent. While the banking agencies’ leverage ratio is not identical to NCUA’s proposed stress test capital ratio, it is the most comparable of the banking capital ratios. NCUA is setting the minimum stress test capital ratio higher than the leverage ratio in recognition of the fact that credit unions cannot raise capital in the form of stockholder equity. Most credit unions can replenish depleted capital only through the retention of earnings, which may be especially difficult in times of stress. Credit unions must, therefore, anticipate any need to retain additional earnings. The stress test process, combined with the 5 percent minimum ratio, prepares them to do this.

The net worth ratio contains components that do not constitute core capital on which a credit union may rely to offset losses. The proposed regulation excludes the following components from the definition of stress test capital ratio:

- assistance through Section 208 of the Federal Credit Union Act,
- subordinated debt for low-income credit unions, and
- the credit union’s NCUSIF deposit.

There are several reasons for these exclusions. Stress tests are intended to show the impact of events on a credit union’s own capital, and therefore will not include assistance provided by NCUA. The largest credit unions are unlikely to be designated as low-income. Only low-income credit unions are authorized by statute to count subordinated debt as capital. In any event, NCUA believes the largest credit unions should be supported by their own capital under stressed conditions. The NCUSIF deposit is carried by credit unions as an asset rather than being expensed. It therefore elevates credit union net worth ratios compared to banks without representing capital on which a credit union may draw to absorb losses from stresses as they occur.

As noted above, if NCUA’s stress test indicates a covered credit union cannot maintain a minimum stress test capital ratio of 5 percent under expected and stressed conditions throughout the quarter stress test period, NCUA will require the credit union to include actions and timeframes for enhancement of stress test capital. These actions may be to accumulate capital, to reduce risks to capital or a combination of the two. If a covered credit union’s stress test capital ratio indicates serious safety and soundness concerns, NCUA will take supervisory actions at its discretion.

Before taking any action on the stress test of a federally insured, state-chartered credit union, NCUA will consult with the applicable state supervisory authority.

\footnote{12 CFR part 702.}
\footnote{See 78 FR 62018 (Oct. 11, 2013).}
The Board notes that the Federal Reserve, OCC, and FDIC require their covered institutions to conduct their own stress testing based on agency-provided baseline, adverse, and severely adverse scenarios. The Board seeks comment on whether NCUA should similarly require covered credit unions to conduct their own stress testing.

**F. Public Disclosure**

The Board also notes that the Federal Reserve, OCC, and FDIC require their covered institutions to publicly disclose the results of their stress tests. The Board recognizes that public disclosure helps to provide valuable information to market participants, enhances transparency, and facilitates market discipline. However, the Board also understands that stress test results can be misinterpreted and lead to inaccurate conclusions about the health of an institution. The Board seeks comment on the benefits and costs associated with credit union-specific disclosures, specific concerns about the possible release of a credit union’s proprietary information, and alternatives to credit union-specific disclosures that could still provide useful information to the membership or the public.

**G. Process Overview.**

Table 1 describes the capital planning and NCUA stress testing process under this proposed rule, including the anticipated general timelines for each step.

### TABLE 1—PROCESS OVERVIEW OF CAPITAL PLANNING AND ANNUAL STRESS TEST REQUIREMENTS UNDER THIS PROPOSED RULE

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 30</td>
<td>&quot;As of&quot; date for covered credit union’s capital plan and NCUA’s stress test data.</td>
</tr>
<tr>
<td>by December 1</td>
<td>NCUA releases scenarios on which it will conduct independent stress tests.</td>
</tr>
<tr>
<td>by March 31</td>
<td>Covered credit union submits capital plan to NCUA.</td>
</tr>
<tr>
<td>by May 31</td>
<td>NCUA provides stress test results to covered credit union.</td>
</tr>
<tr>
<td>by June 30</td>
<td>NCUA approves or rejects capital plan.</td>
</tr>
<tr>
<td>by September 30</td>
<td>Covered credit union must have an NCUA-approved capital plan.</td>
</tr>
</tbody>
</table>

The Board emphasizes that credit union capital planning and NCUA’s stress testing have different timelines. While covered credit unions may choose to perform their own stress tests, NCUA will rely on the independent stress testing described in this proposed rule to measure a covered credit union’s stress test capital ratio. However, if a covered credit union fails the NCUA stress test and must provide a stress test capital enhancement plan under §702.506(e), the credit union must incorporate enhancement plan into the §702.503 capital plan submitted the following year.

### III. REGULATORY PROCEDURES

#### a. Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis of any significant economic impact any proposed regulation may have on a substantial number of small entities (primarily those under $50 million in assets). Because the proposed rule only applies to credit unions with $10 billion or more in assets, it will not have any economic impact on small credit unions.

### b. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or increases an existing burden. For purposes of the PRA, a paperwork burden may take the form of a reporting or recordkeeping requirement, both referred to as information collections. The proposed changes to part 702 impose new information collection requirements. As required by the PRA, NCUA is submitting a copy of this proposal to OMB for its review and approval. Persons interested in submitting comments with respect to the information collection aspects of the proposed rule should submit them to OMB at the address noted below.

#### 1. Estimated PRA Burden

The information collection requirements are found in sections 702.503, 702.504, 702.505, and 702.506 of the proposed rule. Section 702.503(a) requires a covered credit union to develop and maintain a capital plan and to submit the plan to NCUA by March 31 of a given year. Section 702.506(a) further requires a covered credit union’s board of directors or a designated committee to review and approve the covered credit union’s capital plan prior to its submission to NCUA.

Section 702.503(b) provides the list of mandatory elements to be included in the capital plan.

Section 702.504 provides that the senior management of a covered credit union must establish and maintain a system of controls, oversight, and documentation designed to ensure that the capital planning and analysis processes satisfy the requirements in this part.

Section 702.505(d) provides that within 30 calendar days of receipt of a notice of rejection by NCUA of a covered credit union’s capital plan, under section 702.505(c), the covered credit union must update and re-submit its capital plan to NCUA.

Section 702.506(c) requires a covered credit union to provide any relevant qualitative or quantitative information requested by NCUA to conduct the supervisory stress test.

#### Summary of Burden

As of June 30, 2013, there were four FICUs with assets of $10 billion or more.
2. Submission of comments

NCUA considers comments by the public on this proposed collection of information in:
- Evaluating whether the proposed collection of information is necessary for the proper performance of the functions of NCUA, including whether the information will have a practical use;
- Evaluating the accuracy of NCUA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

The PRA requires OMB to make a decision concerning the collection of information contained in the proposed regulation within 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to NCUA on the substantive aspects of the proposed regulation.

Comments on the proposed information collection requirements should be sent to: Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, DC 20503; Attention: NCUA Desk Officer, with a copy to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

c. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. The proposed rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. NCUA has, therefore, determined that this proposal does not constitute a policy that has federalism implications for purposes of the executive order.

d. Assessment of Federal Regulations and Policies on Families


List of Subjects in 12 CFR Part 702

Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board, on October 24, 2013.

Gerard Poliquin,
Secretary of the Board.

For the reasons discussed above, the National Credit Union Administration proposes to amend part 702 as follows:

PART 702—CAPITAL ADEQUACY

§702.501 Authority, purpose, and reservation of authority.

Authority: 12 U.S.C. 1766(a), 1790d.

§702.502 Definitions.

(a) Authority. This subpart is issued by the National Credit Union Administration (NCUA).

(b) Purpose. This subpart requires covered credit unions to develop and maintain capital plans and describes NCUA stress testing and actions on credit union capital plans.

(c) Reservation of authority. Notwithstanding any other provisions of this subpart, NCUA may modify some or all of the requirements of this subpart. Any exercise of authority under this section by NCUA will be in writing and will consider the financial condition, size, complexity, risk profile, scope of operations, and level of regulatory capital of the covered credit union, in addition to any other relevant factors.

Nothing in this subpart limits the authority of NCUA under any other provision of law or regulation to take supervisory or enforcement action, including action to address unsafe and unsound practices or conditions, or violations of law or regulation.

§702.502 Definitions.

For purposes of this subpart—Adverse scenario means a scenario that is more adverse than that associated with the baseline scenario.

Baseline scenario means a scenario that reflects the consensus views of the economic and financial outlook.

Capital plan means a written presentation of a covered credit union’s capital planning strategies and capital adequacy process that includes the mandatory elements set forth in this subpart.

Capital policy means a covered credit union’s written assessment of the principles and guidelines used for capital planning, including analyzing capital, establishing capital levels, describing the strategies for addressing potential capital shortfalls, and describing the internal governance procedures around capital policy principles and guidelines.

Covered credit union means a federally insured credit union whose assets were $10 billion or more on March 31 of the current calendar year.

Planning horizon means the period of at least three years over which the relevant projections extend.

Pre-provision net revenue means the sum of net interest income and non-interest income, less expenses, before adjusting for loss provisions.

Provision for loan and lease losses means the provision for loan and lease losses as reported by the covered credit union on its Call Report.

Scenarios are those sets of conditions that affect the U.S. economy or the financial condition of a covered credit union that NCUA annually uses to conduct stress tests, including, but not limited to, baseline, adverse, and severely adverse scenarios.

Severely adverse scenario means a scenario that overall is more severe than that associated with the adverse scenario.

Stress test means the process to assess the potential impact of expected and stressed economic conditions on the consolidated earnings, losses, and capital of a covered credit union over the planning horizon, taking into account the current state of the covered credit union and the covered credit union’s risks, exposures, strategies, and activities.

Stress test capital means net worth (less assistance provided under Section 671 of the Federal Deposit Insurance Act) less all liabilities of the credit union at the end of a stress test scenario.
§ 702.503 Credit union capital planning.
(a) General requirements—Annual capital planning. (1) A covered credit union must develop and maintain a capital plan.
(2) A covered credit union must submit its complete capital plan to NCUA each year by March 31, or such later date as directed by NCUA. The plan must be based on the credit union’s financial data as of September 30 of the previous calendar year.
(3) The covered credit union’s board of directors or a designated committee thereof must at least annually and prior to submission of the capital plan under paragraph (a)(2) of this section:
(i) Review the credit union’s process for assessing capital adequacy;
(ii) Ensure that any deficiencies in the credit union’s process for assessing capital adequacy are appropriately remedied; and
(iii) Approve the credit union’s capital plan and capital planning policy.
(b) Mandatory elements of capital plan. A capital plan must contain at least the following elements:
(1) A quarterly assessment of the expected sources and levels of capital over the planning horizon that reflects the covered credit union’s financial state, size, complexity, risk profile, scope of operations, and existing level of capital, assuming both expected and unfavorable conditions, including:
(i) Estimates of projected revenues, losses, reserves, and pro forma capital levels, over each quarter of the planning horizon under expected conditions and under a range of unfavorable conditions, appropriate to its financial state, size, complexity, risk profile, and scope of operations; and
(ii) A detailed description of the credit union’s process for assessing capital adequacy.
(2) A discussion of how the covered credit union will, under expected and unfavorable conditions, maintain capital commensurate with its risks.
(3) A discussion of how the covered credit union will, under expected and unfavorable conditions, maintain ready access to funding, meeting its obligations to all creditors and other counterparties and continuing to serve as an intermediary for its members.
(4) The covered credit union’s capital policy.
(5) A discussion of any expected changes to the covered credit union’s business plan that are likely to have a material impact on the credit union’s capital adequacy and liquidity.
(c) Mandatory credit union capital analysis. As a fundamental part of its capital planning process, a covered credit union must, at a minimum, conduct the capital analyses set forth in paragraphs (c)(1) through (3) of this section.
(1) A covered credit union must conduct a sensitivity analysis to evaluate the effect on its capital of changes in variables, parameters, and inputs used by the credit union in preparing its capital plan.
(2) A covered credit union must perform an analysis of the net economic value of the credit union using interest rate risk shocks of at least +/- 300 basis points. This analysis must assume all non-maturity shares have final maturities not exceeding two years.
(3) A covered credit union must analyze the impact of credit risk to capital under unfavorable economic conditions, both separately and in combination with the impact of unfavorable interest rate scenarios.
§ 702.504 Governance of capital planning and analysis.
(a) General requirements. The extent and sophistication of a covered credit union’s governance over its capital planning and analysis process must align with the extent and sophistication of that process. The process must be consistent with the financial condition, size, complexity, risk profile, scope of operations, and level of regulatory capital of the covered credit union. Governance over a covered credit union’s capital planning and analysis process must rest with the credit union’s board of directors. Senior management must establish a comprehensive, integrated, and effective process that fits into the broader risk management of the credit union. Accordingly, senior management responsible for capital planning and analysis must report directly to the credit union’s board of directors or a designated committee of the board. NCUA will assess whether the capital planning and analysis process is sufficiently robust in determining whether to accept a credit union’s capital plan.
(b) Capital analysis policy. The board of directors must review and approve a capital analysis policy, along with procedures to implement it, at least annually in conjunction with the covered credit union’s capital plan. The capital analysis policy must:
(1) State the governance over the capital analysis process, including all the activities that contribute to the analysis;
(2) Articulate consistent and sufficiently rigorous capital analysis practices across the entire credit union;
(3) Specify capital analysis roles and responsibilities, including controls over external resources used for any part of capital analysis (such as vendors and data providers);
(4) Describe the frequency with which capital analyses will be conducted;
(5) State how capital analysis results are used, and by whom, and outline instances in which remedial actions must be taken; and
(6) Require review, at least annually, and update the capital analysis process as necessary to ensure that it remains current with changes in market conditions, credit union products and strategies, credit union exposures and activities, the credit union’s established risk appetite, and industry practices.
§ 702.505 NCUA action on capital plans.
(a) Timing. NCUA will notify the covered credit union of the acceptance or rejection of its capital plan by June 30 of the calendar year in which the capital plan was submitted.
(b) Grounds for rejection of capital plan. NCUA may reject a capital plan if it determines that:
(1) The covered credit union has material unresolved supervisory issues associated with its capital planning process;
(2) The assumptions and analysis underlying the covered credit union’s capital plan, or the covered credit union’s methodologies for reviewing the robustness of its capital adequacy, are not reasonable or appropriate;
(3) Data utilized for analysis is insufficiently detailed to capture the risks of the covered credit union, or the data lacks integrity; or
(4) The covered credit union’s capital planning process constitutes an unsafe or unsound practice, or would violate any law, regulation, NCUA order, directive, or any condition imposed by, or written agreement with, NCUA. In determining whether a capital plan would constitute an unsafe or unsound practice, NCUA considers whether the covered credit union is and would remain in sound financial condition after giving effect to the capital plan.
(c) Notification in writing. NCUA will notify the credit union in writing of the reasons for a decision to reject a capital plan.
(d) Re-submission of a capital plan. If NCUA rejects a credit union’s capital plan, the credit union must update and
provide NCUA with any relevant qualitative or quantitative information requested by NCUA to conduct the stress test under this section.

(d) Stress test results. NCUA will provide each covered credit union with the results of the stress test by May 31 of the year following the September 30 “as of” testing date.

(e) Supervisory actions. If NCUA stress tests show that covered credit union does not have the ability to maintain a stress test capital ratio of 5 percent or more on a pro forma basis under expected and stressed conditions throughout the 9-quarter horizon, the credit union must provide NCUA, within 60 days of receipt of the stress test results, a stress test capital enhancement plan showing how it will meet that target. Failure to do so will subject a covered credit union to supervisory actions on the part of NCUA.

(f) Federally insured, state-chartered credit unions. Before taking any action under this section on a covered credit union operating without an NCUA-approved capital plan after September 30 of the year in which the plan was submitted will be subject to supervisory actions on the part of NCUA.

§ 702.506 Annual supervisory stress testing.

(a) NCUA tests. NCUA will conduct an annual stress test of each covered credit union using baseline, adverse, and severely adverse scenarios. NCUA will provide a description of those scenarios by December 1 of a calendar year and will conduct the stress test using the credit union’s financial data as of September 30 of that year. NCUA stress test analysis will take into account all relevant exposures and activities of a credit union to evaluate its ability to absorb losses in specified scenarios over a 9-quarter horizon. The minimum target stress test capital ratio for covered credit unions is 5 percent.

(b) Potential impact on capital. In conducting a stress test under this subpart, during each quarter of the stress test horizon, NCUA will estimate the following for each scenario for each covered credit union:

(1) Pre-provision net revenues, loan and lease loss provisions, and net income; and

(2) The potential impact on the stress test capital ratio, incorporating the effects of any capital action over the stress test horizon and maintenance of an allowance for loan losses appropriate for credit exposures throughout the horizon. NCUA will conduct the stress test without assuming any risk mitigation actions on the part of the covered credit union, except those existing and identified as part of the covered credit union’s balance sheet, or off-balance sheet positions, such as assets sales or derivatives positions, on the date of the stress test.

(c) Information collection. Upon request, the covered credit union must satisfy the applicable state supervisory authority.

Any covered credit union submitting a stress test enhancement plan showing how it will meet the target will subject a covered credit union to supervisory actions on the part of NCUA.

(f) Federally insured, state-chartered credit unions. Before taking any action under this section on a federally insured, state-chartered credit union, NCUA will consult with the applicable state supervisory authority.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA—2013–N–0001]

Medical Gas Regulation Review; Announcement of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting on whether any changes to Federal drug regulations are necessary for medical gases. The topic to be discussed is whether any changes to the Federal drug regulations are necessary for medical gases as part of the implementation of the Food and Drug Administration Safety and Innovation Act (FDASIA).

Date and Time: The meeting will be held on December 6, 2013, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early.

Location: The meeting will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating (please note that all visitors to the White Oak Campus must enter through Building 1). The meeting is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.


Registration and Requests for Oral Presentations: If you wish to make an oral presentation, you must register by submitting your name, title, firm name, address, telephone, email address, and FAX number, to Mary Gross (see Contact Persons) by December 2, 2013. Please also provide the type of organization you represent (e.g., industry, consumer organization), and a brief summary of your remarks (including the discussion topic(s) that will be addressed).

FDA will try to accommodate all persons who wish to make a presentation; however, the duration of each speaker’s presentation may be limited by time constraints. FDA will notify registered presenters of their scheduled presentation times. Persons registered to speak should check in at least 1 day before the meeting and are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called may not be permitted to speak at a later time. An agenda of the meeting will be made available at least 3 days before the meeting at http://www.fda.gov/Drugs/NewEvents/ucm370351.htm.

This public meeting will be Webcast and the URL will be posted at http://www.fda.gov/Drugs/NewEvents/ucm370351.htm at least 1 day before the meeting. A video record of the public meeting will be available at the same Web site address for 1 year. If you need special accommodations because of disability, please contact Mary Gross (see Contact Persons) at least 7 days in advance.