Consumer Representative Members Public Meeting

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Rockville, MD 30 April 2010

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Consumer Representative Nomination Process

Major points to remember

- 1. Track the federal register notices requesting nominations for each specific committee
- 2. Submit nominations
- 3. Consumer groups may submit request to participate in the nomination process
- 4. Consumer Groups participating, return ballot

Consumer Representative Nomination Process

21 CFR Sec. 14.84 (a)(1)-(5)

Nominations and selection of nonvoting members of standing technical advisory committees.

At least 6 months in advance of future vacancies a request for nominations of voting and non-voting members of FDA advisory committees is initiated by the Designated Federal Officer of the advisory committee.

Consumer Representative Nomination Process Federal Register Announcement

21 CFR Sec. 14.84

- (b) members are normally limited to one person selected by consumer groups and organizations
- (c) To select a nonvoting member to represent consumer interests, the Commissioner publishes a notice in the Federal Register requesting nominations for each specific committee, or subcommittee, for which nonvoting members are to be appointed.

also applies to voting representatives

Federal register notice can be found on the FDA AC website http://www.fda.gov/AdvisoryCommittees/default.htm





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About Advisory Committees

The Food and Drug Administration, to assist in its mission to protect and promote the public health, uses 49 committees and panels to obtain independent expert advice on scientific, technical, and policy matters.



About Advisory Committees

How to become a member of an advisory committee, and the laws, regulations, and guidances that govern the committees.

Committees & Meeting Materials

Committee information, charter, meeting materials, committee roster, etc.

Advisory Committee Calendar

Confirmed and Tentatively Scheduled Meetings

Recently Updated Advisory Committee Materials

Meeting announcements, briefing materials, requests for nominations, and other important information

Search Advisory Committees

Resources for You

 Applying for Membership



Spotlight

- April 30, 2010 Public Meeting on Voting and Nonvoting Consumer Representative Members on Public Advisory Committee Meeting and Panels
- FDA Announces Draft Revised Guidance on Transparency and Advisory Committees
- · Notice of Availability -Draft Guidance: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers (PDF - 18KB)
- Advisory Committee Calendar
- Please Take Our Short Survey

Advisory Committees

- Blood, Vaccines and Other Biologics
- Drugs
- Food Advisory Committee
- Medical Devices

Consumer Representative Nomination Process Submit Nomination

21 CFR Sec. 14.84(1)

A period of 30 days will be permitted for submission of nominations for that committee or subcommittee. Interested persons may nominate one or more qualified persons to represent consumer interests.

- •Although nominations from individuals will be accepted, individuals are encouraged to submit their nominations through consumer organizations
- •Nominations of qualified persons for general consideration may be made at any time.
- •All nominations are to be submitted in writing to the Advisory Committee Oversight and Management Staff

White Oak Building 32, Rm 5129

10903 New Hampshire Ave Silver Spring Md 20993

E mail: CV@OC.fda.gov

Consumer Representative Nomination Process Submit Nomination

21 CFR Sec. 14.84(2)

A complete curriculum vitae of any nominee is to be included.

Nominations must include:

- Nominees name (complete contact information)
- Name of committee of interest

Recommend:

- A letter of recommendation
- •state that the nominee is aware of the nomination and willing to serve
- •Cover letter that includes the consumer or community based organization(s) OR work which the candidate can demonstrate active participation

Consumer Representative Nomination Process Consumer Group Participation

21 CFR Sec. 14.84(3)

The Advisory Committee Oversight and Management Staff

- will compile a list of organizations whose objectives are to promote, encourage, and contribute to the advancement of consumer education and to the resolution of consumer problems.
- •All organizations listed are entitled to vote upon the nominees.
- •The list will include organizations representing the public interest, consumer advocacy groups, and consumer/health branches of Federal, State, and local governments.
- •Any organization that meets the criteria may be included on such list on request.

Consumer Representative Nomination Process Designated Federal Officer

21 CFR Sec. 14.84(4)

The executive secretary (DFO), will review the list of nominees and select three to five qualified nominees to be placed on a ballot.

- Names not selected will remain on a list of eligible nominees and be reviewed periodically by ACOMS to determine continued interest.
- Upon selection of the nominees to be placed on the ballot, the curriculum vitae for each of the nominees will be sent to each of the organizations on the list together with a ballot to be filled out and returned within 30 days.
- After the time for return of the ballots has expired, the ballots will be counted and the nominee who has received the highest number of votes will be selected as the member representing consumer interests for that particular advisory committee

Consumer Representative Nomination Process Resignations

21 CFR Sec. 14.84(5)

If a member representing consumer interests resigns or is removed before termination of the committee on which the member is serving, the following procedures will be used to appoint a replacement to serve out the term of the former member:

(i) The Commissioner will appoint the runner up, in order of number of ballots received, on the original ballot submitted to fill the vacancy. If the runner up is no longer willing to serve as a member, then the next runner up will be appointed.

Consumer Representative Nomination Process Resignations

21 CFR Sec. 14.84(5)

- (ii) If none of the nominees on the original ballot is willing to serve, or if there was only one nominee on the original ballot, ACOMS will contact by telephone eligible individuals whose names have been submitted in the past as candidates for membership as representatives of consumer interests.
- The curricula vitae of these persons, together with a ballot, will be sent to a representative number of consumer organizations that have been determined to be eligible to vote for consumer representatives
- After 4 days have elapsed, ACOMS will contact the consumer organizations by telephone and elicit their votes. The candidate who has received the highest number of votes will be selected.

Consumer Representative Nomination Process Consumer Group Participation

- 1. Groups respond to the Federal register notice
- 2. Groups Submit Nominations
- 3. Include a statement that the group is requesting to participate in the nomination process (include the name and contact information of the point person
- 4. The group will receive each nominees' packet of information that includes a CV, recommendation letter, ballot
- 5. Groups must return the ballot
- 6. ACOMS will notify group and individuals of results

FDA Advisory Committees Need YOU!

Thank you