(nnn) name

(ema) Exhibit marked & admitted

(exm) exhibit marked

(exa) exhibit admitted (1 through 100, A through Z?)

(ee1 through ee6) examination/headings

(e1c through e6c) examination/headings continued

(sbb) sidebar begins

(sbe) sidebar ends

(sbn) sidebar

(rrr) recess

(jen) jury enter

(jex) jury exit

(pjn) prospective jury enter

(pjx) prospective jury exit

(ppp) pause

(wsu) witness summoned

(wsw) witness sworn

(aa1) argument party1

(aa2) argument party 2

(ar1) rebuttal party1

(ar2) rebuttal party2

(ao1) opening party1

(ao2) opening party2

(ac1) closing party1

(ac2) closing party2

(vup) video played

(vub) video began

(vue) video ends

(aup) audio played

(aub) audio began

(aue) audio ends

(crr) court's ruling

(nrp) no responsee (janet too)

(rrl) lunch break

(ppp) Pause

(ppr) paulse And review

(otr) off the record

(dtr) discussion held off the record

(wxu) witness excused

(pcc) parties confer

(ccc) counsel confer

(cco) call case outside jury

(cci) call case in presence of jury

For topics such as those being discussed at today's meeting, there are often a variety of opinions, some of which are quite strongly held.

Our goal is that today's meeting will be a fair and open forum for discussion of these issues, and that individuals can express their views without interruption. Thus, as a gentle reminder, individuals will be allowed to speak into the record only if recognized by the Chair. We look forward to a productive meeting.

In the spirit of the Federal Advisory Committee Act and the Government in the Sunshine Act, we ask that the advisory committee members take care that their conversations about the topic at hand take place in the open forum of this meeting.

We are aware that members of the media are anxious to speak with the FDA about these proceedings. However, the FDA will refrain from discussing the details of this meeting with the media until its conclusion.

For the convenience of the media representatives, i would like to identify the FDA press contact, Yolanda Fultz-Morris. That's her name. You can look her up. i'm sure she'll be here later, if present. Also, the committee is reminded to please refrain from discussing the meeting topic during breaks or lunch. Thank you.

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The Food and Drug Administration is convening today's meeting of the Anti-Infective Drugs Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the industry representative, all members and temporary voting members of the committee are special government employees or regular federal employees from other agencies and are subject to federal conflict of interest laws and regulations.

The following information on the status of this committee's compliance with federal ethics and conflict of interest laws, covered by but not limited to those found at 18 U.S.C., Section 208 and Section 712 of the Food, Drug, and Cosmetic Act, is being provided to participants in today's meeting and to the public.

FDA has determined that members of this committee are in compliance with the federal ethics and conflict of interest laws.

Under 18 U.S.C., Section 208, Congress has authorized FDA to grant waivers to special government employees who have potential financial conflicts, when it is determined that the agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Under Section 712 of the FD&C Act, Congress has authorized FDA to grant waivers to special government employees and regular federal employees with potential financial conflicts when necessary to afford the committee essential expertise.

Related to the discussion of today's meeting, members and temporary members of this committee have been screened for potential financial conflicts of interest of their own, as well as those imputed to them, including those of their spouses or minor children, and for purposes of 18 U.S.C. Section 208, their employers.

These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves discussion of clinical trial design issues for the development of anti-bacterial drugs for the treatment of community-acquired bacterial pneumonia and the draft document entitled, "Guidance for Industry: Community-Acquired Bacterial Pneumonia, Developing Drugs for Treatment," published in 2009, March.

This is a particular matters meeting, during which general issues will be discussed. The committee will not be voting. Based on the agenda for today's meeting and all financial interests reported by the committee members and temporary members, no conflict of interest waivers have been issued.

A copy of this statement will be available for review at the registration table during the meeting and will be included as part of the official transcript.

To ensure transparency, we encourage all standing committee members and temporary members to disclose any public statements that they have made concerning the topic at issue.

With respect to FDA's invited industry representative, we would like to disclose that Dr. John Rex is participating in this meeting as a non-voting industry representative, acting on behalf of regulated industry. Dr. Rex's role at this meeting is to represent industry in general and not any particular company. Dr. Rex is employed by AstraZeneca.

With regard to FDA's guest speakers, the agency has determined that the information to be provided by these speakers is essential. The following relevant interests are being made public to allow the audience to evaluate objectively any presentation and/or comments made by the speakers.

Dr. Barry Eisenstein is employed by Cubis Pharmaceuticals and holds stocks in Cubis Pharmaceuticals and Eli Lilly.

Dr. Bartlett has personal and financial relationships with Epocrates, Medscape, and Up-to-Date. Medscape, Up-to-Date, and Epocrates provide physicians and other health professions with integrated medical information and educational tools on a variety of topics, including community-acquired pneumonia.

Dr. Thomas File has received funding from Forest Laboratories, Pfizer, and Cempra Pharmaceuticals for clinical research of drugs for the treatment of community-acquired pneumonia. In addition, he has served as a scientific advisor or consultant for Bayer, Diichi/Sankyo, Merck, Pfizer, GlaxoSmithKline, Nabriva Therapeutics, and Tetraphase Pharmaecuticals.

Dr. Diana Zuckerman holds stock in Johnson and Johnson. Dr. Zuckerman has been an outspoken critic at public meetings and media regarding a range of product safety and efficacy issues for J&J products, as well as other companies' products.

We would like to remind members and temporary members that, if the discussions involve any other products or firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, participants need to exclude themselves from such involvement and their exclusion will be noted for the record.111

FDA encourages all other participants to advise the committee of any financial relationships they may have with the affected firms at issue. Thank you.

L1: For topics such as those being discussed at today's meeting, there are often a variety of opinions, some of which are quite strongly held. Our goal is that today's meeting will be a fair and open forum for discussion of these issues, and that individuals can express their views without interruption. Thus, as a general reminder, individuals will be allowed to speak into the record only if recognized by the Chair. We look forward to a productive meeting. In the spirit of the Federal Advisory Committee Act and the Government in the Sunshine Act, we ask that the advisory committee members take care that their conversations about the topics at hand take place in the open forum of the meeting.

We are aware that members of the media are anxious to speak with the FDA about these proceedings. However, FDA will refrain from discussing the details of this meeting with the media until its conclusion. Also, the committee is reminded to please refrain from discussing the meeting topics during breaks. Thanks. Caryn?

L2: The Food and Drug Administration is convening today's meeting of the Tobacco Products Scientific Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. All members of the committee are special government employees and are subject to federal ethics, and conflict of interest laws, and regulations covered by but not limited to those found at 18 U.S.C., Section 208 and Section 712 of the Food, Drug, and Cosmetic Act.

FDA has determined that members of this committee are in compliance with the federal ethics and conflict of interest laws.

Under 18 U.S.C., Section 208, Congress has authorized FDA to grant waivers to special government employees who have potential conflicts of interest, when it is determined that the agency's need for a particular individual's services outweighs his or her potential financial conflict of interest. Under Section 712 of the FD&C Act, Congress has authorized FDA to grant waivers to special government employees with potential financial conflicts, when necessary, to afford the committee essential expertise.

Related to the discussion of today's meeting, members of this committee have been screened for potential financial conflicts of interest of their own, as well as those imputed to them, including those of their spouses or minor children, and for purposes of 18 U.S.C. Section 208, their employers.

These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves discussion and review of trade secret and/or confidential information. 5 U.S. 55b(c)(4) -- during this session, the committee will discuss confidential data provided by the Federal Trade Commission and the tobacco industry. Based on the agenda for today's meeting and all financial interests reported by the committee members, no conflict of interest waivers have been issued in connection with this meeting.

We want to remind the committee that the information discussed during the session is confidential and must not be disclosed or discussed with others outside this forum. FDA encourages all other participants to advise the committee of any financial relationships that they may have with any firms at issue. I would like to remind everyone present to please turn off your cell phones if you have not already done so. Even if they're on at all, even without the ringtone, they interfere with the PA system. And I would also like to identify the FDA press contact, Tesfa Alexander.

Related to today's closed session, i just want to make a few other statements. This session of the advisory committee has been closed to the public to allow you, the committee members, to discuss confidential commercial information that cannot be made publicly available. During the course of preparing the menthol report, members of the writing group have received commercial confidential information during a teleconference by viewing the slides via Adobe Connect. Some writing group members requested that certain confidential information be sent to them for further review.

Today, you will all receive additional commercial confidential information during this closed session. The commercial confidential information consists of information that was submitted by the tobacco industry under Section 904(B) of the Family Smoking Prevention and Tobacco Control Act in response to the May 26th, 2010 letter from the FDA, which relayed your requests for information from the inaugural TPSAC meeting in March 2010.

During this morning's closed session, you'll receive commercial confidential information through presentations and may ask questions of the presenters to clarify your understanding of that information. There can be discussion of the commercial confidential information during this closed session. But any discussion of material that is not confidential must take place in this afternoon's open session.

However, you must not reference any of the information that has been determined to be commercial confidential during this afternoon's open session or tomorrow in any other forum. We understand that this is somewhat confusing. To help with keeping things straight, we've printed materials that contain confidential materials on colored paper.

We will also provide you with a publicly releasable version of Chapters 3 and 6 to use in this afternoon's discussion. Please remember that if you wish to include commercial confidential information in the menthol report, clearly mark it in all draft chapters and in your final version. We will have the draft chapters and the final report reviewed by our Freedom of Information staff and will prepare a redacted version for public distribution. Please be aware that this information will remain confidential indefinitely.

And if you choose to keep copies, they must be kept in a locked cabinet and not shared with anyone. We have a box here to collect the paper copies for shredding if you do not wish to have the responsibility of maintaining the confidential information. We will also collect confidential information at each of the subsequent TPSAC meetings. Once the report is finalized, all copies of confidential information must be returned to FDA. Thank you.

L2: The Food and Drug Administration is convening today's meeting of the Tobacco Products Scientific Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. All members of the committee are special government employees and are subject to federal ethics, and conflict of interest laws, and regulations covered by but not limited to those found at 18 U.S.C., Section 208 and Section 712 of the Food, Drug, and Cosmetic Act.

FDA has determined that members of this committee are in compliance with federal ethics and conflict of interest laws.

Under 18 U.S.C., Section 208, Congress has authorized FDA to grant waivers to special government employees who have potential financial conflicts of interest, when it is determined that the agency's need for a particular individual's services outweighs his or her potential financial conflict of interest. Under Section 712 of the FD&C Act, Congress has authorized FDA to grant waivers to special government employees with potential financial conflicts of interest, when necessary, to afford the committee essential expertise.

Related to the discussion of today's meeting, members of this committee have been screened for potential financial conflicts of interest of their own, as well as those imputed to them, including those of their spouses or minor children, and for purposes of 18 U.S.C. Section 208, their employers.

These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves discussion and review of trade secret and/or confidential information. 5 U.S.C 52b(c)(4) -- during this session, the committee will discuss confidential data provided by the Federal Trade Commission and the tobacco industry. Based on the agenda for today's meeting and all financial interests reported by the committee members, no conflict of interest waivers have been issued in connection with this meeting.

We want to remind the committee that the information discussed during the session is confidential and must not be disclosed or discussed with others outside this forum. FDA encourages all other participants to advise the committee of any financial relationships that they may have with `any firms at issue. Thank you. I would also like to remind everyone present to please silence your cell phones if you have not already done so. I would also like to identify the FDA press contact. Dr. Alexander is over there. Thank you.

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Both the Food and Drug Administration, the FDA, and the public believe in a transparent process for information gathering and decision making. To ensure such transparency of the open public hearing session of the advisory committee meeting, FDA believes it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with a sponsor, its product, and if known, its direct competitors. For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance of the meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the committee if you do not have any such financial relationships.

If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking. The FDA and this committee place great importance in the open public hearing process. The insights and comments provided can help the agency and this committee in their consideration of the issues before them.

One of our goals today is for this open public hearing to be conducted in a fair and open way, where every participant is listened to carefully, and treated with dignity, courtesy, and respect. Therefore, please speak only when recognized by the chair. Thank you for your cooperation.

For topics such as those being discussed at today's meeting, there are often a variety of opinions, some of which are quite strongly held. Our goal is that today's meeting will be a fair and open forum for discussion of these issues, and that individuals can express their views without interruption.

Thus, as a general reminder, individuals will be allowed to speak into the record only if recognized by the Chair. We look forward to a productive meeting. In the spirit of the Federal Advisory Committee Act and the Government in the Sunshine Act, we ask that the advisory committee members take care that their conversations about the topics at hand take place in the open forum of the meeting.

We are aware that members of the media are anxious to speak with the FDA about these proceedings. However, FDA will refrain from discussing the details of this meeting with the media until its conclusion. Also, the committee is reminded to please refrain from discussing the meeting topics during breaks or lunch. Thank you.

L16: Good morning. The Food and Drug Administration is convening today's meeting of the Endocrinologic and Metabolic Drugs Advisory Committee under the authority of the Federal Advisory Committee Act of 1972.

FDA With the exception of the industry representative, all members and temporary voting members of the committee are special government employees or regular federal employees from other agencies and are subject to federal conflict of interest laws and regulations. The following information on the status of this committee's compliance with the federal ethics and conflict of interest laws, covered by but not limited to those found at 18 U.S.C. Section 208 and Section 712 of the Federal Food, Drug, and Cosmetic Act is being provided to participants in today's meeting and to the public.

FDA has determined that members and temporary voting members of this committee are in compliance with the federal ethics and conflict of interest laws.

Under 18 U.S.C., Section 208, Congress has authorized FDA to grant waivers to special government employees and regular federal employees who have potential financial conflicts, when it is determined that the agency's need for a particular individual's services outweighs his or her potential financial conflict of interest. Under Section 712 of the FD&C Act, Congress has authorized FDA to grant waivers to special government employees and regular federal employees with potential financial conflicts when necessary to afford the committee essential expertise.

Related to the discussion of today's meeting, members and temporary voting members of this committee have been screened for potential financial conflicts of interest of their own, as well as those imputed to them, including those of their spouses or minor children, and for purposes of 18 U.S.C. Section 208, their employers.

These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves discussion of the safety and efficacy of new drug application NDA22-580, proposed trade name Qnexa. It's a combination of phentermine and topiramate, a controlled-release capsule by Vivus, Incorporated, as an addition to diet and exercise for weight management in a patient with a body mass index equal to or greater than 30 kilograms per square meter or a body mass index equal to or greater than 27 kilograms per square meter if accompanied by weight-related co-morbidity.

This is a particular matters meeting, during which specific matters related to the Vivus product Qnexa will be discussed. Based on the agenda for today's meeting and all financial interests reported by the committee members and temporary voting members, no conflict of interest waivers have been issued in connection with this meeting.

To ensure transparency, we encourage all standing committee members and temporary voting members to disclose any public statements that they have made concerning the topic at issue.

With respect to FDA's invited industry representative, we would like to disclose that Dr. Mads Rasmussen is participating in this meeting as a non-voting industry representative, acting on behalf of regulated industry. Dr. Rasmussen's role at this meeting is to represent industry in general and not any particular company. Dr. Rasmussen is employed by Novo Nordisk.

We would like to remind members and temporary voting members that if the discussion involves any other product or firm not already on the agenda for which the FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement and their exclusion will be noted for the record.

FDA encourages all other participants to advise the committee of any financial relationships that they may have with any firms at issue. Thank you.

I'd like to remind public observers at this meeting that while this meeting is open for public observation, public attendees may not participate except at the specific request of the panel.

Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency of the advisory committee meeting, FDA believes it is important to understand the context of an individual's presentation.

For this reason, FDA encourages all participants, including the sponsor's non-employee presenters, to advise the committee of any financial relationship that they may have with the firm at issue, such as consulting fees, travel expenses, honoraria, and interest in the sponsor, including equity interests, and those based upon the outcome of the meeting.

Likewise, FDA encourages you, at the beginning of your presentation, to advise the committee if you do not have any such financial relationships.

If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

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So the committee will now turn its attention to address the task at hand, the careful consideration of the data before the committee as well as the public comments made earlier.

We will now review the questions to the committee and have panel discussions. I would like to remind public observers at this meeting that, while this meeting is open for public observation, public attendees may not participate except at the specific request of the panel.

We will be using an electronic voting system for this meeting. Once we begin the vote, the buttons will begin flashing and will continue to flash even after you have entered your vote. Please press the button firmly that corresponds to your vote.

If you are unsure of your vote or you wish to change your vote, you may press the corresponding button until the vote is closed. After everyone has completed their vote, the vote will be locked in.

The vote will then be displayed on the screen. The DFO will read the vote on the screen into the record. Next, we will go around the room and each individual who voted will state their name and their vote into the record. You can also state the reason why you voted as you did if you would like to.

We will continue in this same manner until all questions have been answered or discussed.