EDUCATION AND TRAINING

Accreditation — Continuing Education

CONTENTS

PURPOSE

- This MAPP describes the policies, procedures, and responsibilities for the accreditation of education and training activities conducted by the Center for Drug Evaluation and Research (CDER). These procedures are intended to ensure that all CDER education and training activities approved for continuing medical education credit and/or continuing pharmaceutical education credit meet the standards and criteria for quality established by the Accreditation Council for Continuing Medical Education and the American Council on Pharmaceutical Education. This replaces MAPP 4550.2, Staff College, which has been withdrawn.

BACKGROUND

- CDER is an approved provider of continuing medical education (CME) by the Accreditation Council for Continuing Medical Education (ACCME), and an approved provider of continuing pharmaceutical education (CPE) by the American Council on Pharmaceutical Education (ACPE). CDER's continuing education program supports and assists physicians, pharmacists, and scientists by providing learning opportunities in essential and advancing areas of the medical sciences and cutting-edge biopharmaceutical technologies, in accordance with the stated mission of CDER to ensure that safe and effective drugs are available to the American people.

  The goal of CDER's continuing education program is to meet the individual and group educational needs of CDER's multidisciplinary health professionals by:

- Offering educational opportunities that provide the knowledge and skills needed to make better-informed scientific and regulatory decisions
- Exploring and promoting active learning opportunities through the use of innovative technologies
- Conducting an annual program review and implementing improvement as needed

Because the work of CDER includes the review of investigational drug applications, new drug applications, abbreviated new drug applications (generic equivalents), postmarketing epidemiological studies, and compliance with drug regulatory law and postmarketing surveillance, the activities presented include policy training and scientific education related to drug development, drug evaluation, and postmarketing drug oversight. To provide these activities, CDER engages in joint sponsorships with organizations that share CDER's mission or educational objectives. Delivery methods include traditional live instructor-led, computer-based, and Web-based instructional formats.

The primary audience for continuing education at CDER is made up of physicians, pharmacists, and scientists involved in drug evaluation. A secondary audience includes health care professionals who need knowledge in this area.

Continuing education activities include courses, seminars, scientific rounds, workshops, journal clubs, enduring materials, and special topic presentations.

REFERENCES

- The ACCME's Accreditation Handbook, August 1999
- The ACPE's Continuing Education Manual: Continuing Pharmaceutical Education Provider Approval Program, June 1996
- The Alliance for Continuing Medical Education Handbook
- Committee for Advanced Scientific Education By Laws, October 1998, amended December 2001
- *Federal Register* notice, Final Guidance on Industry-Supported Scientific and Educational Activities (62 FR 64074, December 3, 1997)

DEFINITIONS

Accreditation: The status conferred by an accrediting body such as the Accreditation Council for Continuing Medical Education or the American Council on Pharmaceutical Education to entities that meet specific criteria for developing and delivering quality continuing education programs.

Accreditation Council for Continuing Medical Education (ACCME): The not-for-profit agency responsible for the identification, development, and promotion of standards for quality continuing medical education.

American Council on Pharmaceutical Education (ACPE): The not-for-profit agency responsible for the identification, development, and promotion of standards for quality continuing

pharmaceutical education. ACPE's Accreditation Provider Program is designed to ensure pharmacists, boards of pharmacy, and other members of pharmacy's community of interests of the quality of continuing pharmacy education programs.

Accreditation Program Administrator (APA): The individual in CDER responsible for the direction of the accreditation program and authorized to approve an educational activity for continuing medical education and/or continuing pharmacy education credit.

Accreditation Program Manager (APM): The individual in CDER responsible for the administrative management of the accreditation program. This includes maintenance of files and records and the issuance of continuing education (CE) certificates.

Accreditation Request Form: A form summarizing the planning, content, evaluation, and review of an educational activity proposed for accreditation.

Accredited sponsor: An organization accredited for its overall continuing education program. The accredited provider is responsible for determining needs, planning, financing, designing, promoting, implementing, evaluating, and certifying courses.

Activity: A single continuing education event.

Committee for Advanced Scientific Education (CASE): The principal scientific educational advisory committee for CDER. CASE-initiated educational activities include CDER scientific seminars, scientific rounds, advanced scientific courses, and workshops.

Continuing medical education (CME): Educational activities that maintain, develop, or increase the knowledge, skills, professional performance, and relationships that a physician uses to provide service for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

Continuing pharmaceutical education (CPE): Educational activities on topics pertinent to the contemporary practice of pharmacy that include, but are not limited to, the social, economic, behavioral, legal, administrative, and managerial aspects of pharmacy practice and health care; the properties and actions of drugs and dosage forms; the etiology, characteristics, therapeutics, and prevention of disease states; the pharmaceutical monitoring and management of patient therapy; and other information unique to the practice of pharmacy.

Continuing education program: Any form of educational experience supporting continued learning that targets an audience of physicians, pharmacists or other public health professionals and that is consistent with the definitions of CME and CPE.

Enduring materials: Printed, recorded, Internet-based, or computer-assisted instructional materials that may be used over time at various locations and that in themselves constitute a planned CE activity. Examples include programmed texts, audiotapes, videotapes, and computer-assisted instructional materials used alone or in combination with written materials.

Joint sponsorship: An arrangement in which an accredited sponsor joins with and lends its accreditation status to a non-accredited entity. The accredited sponsor maintains the same responsibility it would if it were the sole sponsor. All other sponsorship criteria apply.

POLICY

- The goal of CDER's continuing education program is to identify and meet the educational needs of CDER's multidisciplinary health professionals by providing the knowledge and skills needed for them to make better-informed scientific and regulatory decisions. CDER will ensure balance, independence, objectivity, and scientific rigor in all directly sponsored or jointly sponsored educational activities.

A. General

- Learning objectives and expected learning outcomes are required for each continuing education activity.

- Any continuing education activities for which CPE is requested must be submitted at least 60 days prior to the event.

- An activity for which accreditation is requested will not be advertised or promoted for CME and/or CPE until the Accreditation Program Administrator has approved it.

- The Accreditation Request Form must be used in the planning, review, and approval of all continuing education activities for which CME and/or CPE is requested.

- Each completed activity will be evaluated at its completion to determine whether it met the education need identified.

B. Commercial Support

- When commercial funding or resources are accepted from another organization, the following conditions must be met.

1. CDER will ensure (1) that the activity is free of commercial bias for or against any product, and (2) that activities related to commercial products will present objective information about those products, based on generally accepted scientific methods.

2. CDER will be responsible for the design and development of the activity. A commercial supporter may assist with preparation, but the content and materials will remain the ultimate responsibility of CDER. None of the materials will advance the proprietary interests of the commercial supporter.

3. CDER may seek assistance from an outside source, but acceptance of advice about speakers, content, or other educational matters will not be a condition of support.

4. Only CDER can authorize a commercial supporter to disseminate information about a CE activity. The content of such information is the responsibility of CDER and must be identified as developed by CDER.

5. When CDER offers activities prepared by commercial entities, those activities must adhere to all ACCME and ACPE standards.

- When CE includes identifying products, reporting on research, or discussing unlabeled uses of products, CDER will ensure that a balanced view of therapeutic options is presented. Use of generic names is preferable to the use of trade names. If trade names are used, those of several companies, rather than that of a single supporting company, should be used. CDER will require commercial entities presenting scientific research to provide documentation confirming the scientific objectivity of the presentation and ensuring conformance with accepted standards of experimental design, data collection, and analysis.

- CDER is responsible for the funding arrangements of the CE activity. When CDER receives commercial support, a signed written agreement between CDER and the commercial supporter must be prepared. This agreement will describe the purposes, terms, and conditions of the joint sponsorship or co-sponsorship arrangement. In addition, the agreement will specifically address CDER's responsibility for the content, quality, and scientific integrity of the CE activity. The agreement will also include acknowledgement of funds received from the commercial supporter for a specific CE activity.

C. Determination of Credit

- For live programs, CDER will total the number of instructional hours from the final agenda of an activity, not including registration, breaks, or lunches. Organized and structured instruction is defined as content related to the learning objectives for the activity. Evaluation activities are also considered in the overall determination of credit. An instructional hour will consist of 50 to 60 minutes of organized continuing education.

- For enduring materials, home study programs, and other mediated instructional activities, the amount of educational credit will be determined by using the Mergener Formula (Attachment C: Determination of Credit for an Enduring Material).

- Credit hours to be awarded for participation and criteria for successful completion of a CE activity will be determined and made known by CDER in advance of offering the activity.

D. Enduring Materials

- CDER will be responsible for the quality and content of enduring material and/or home study programs. Any commercial acknowledgement in enduring materials and/or home study programs must meet the following requirements.

  1. Product-specific advertising of any type is prohibited.
  2. Commercial support must be acknowledged, and this acknowledgement must be placed at the beginning of the enduring material.
  3. Any institutional acknowledgement may state the name, mission, and areas of clinical involvement of the company or institution and may include corporate logos and slogans, if they do not promote products.

- Enduring materials and/or home study programs will communicate the following information to participants:

1. Principal faculty and their credentials
2. Medium or combination of media used
3. Method of physician and/or pharmacist participation in the learning process
4. Estimated time to complete the educational activity
5. Number of designated credit and/or contact hours
6. Criteria for earning credit and obtaining a certificate of credit
7. Dates of original release and most recent review or update

- Internet-provided instruction programs will inform the learner about the following:

1. The software and hardware needed to participate
2. The method for contacting CDER if they have questions about the Internet activity
3. CDER's policy on privacy and confidentially for CME and/or CPE activities it provides on the Internet
4. Documentation of compliance with copyright law, if applicable

E. Faculty Disclosure (See Attachment D)

- CDER will disclose to the participants of the CE activity any financial interest or relationship a speaker has with a manufacturer or a commercial product discussed in the presentation. The information on disclosure, the information that a speaker has no relationships to disclose, or the information that the speaker refuses to disclose a relationship must be provided to the participants prior to the activity. The intent of this disclosure is not to imply that such a relationship is improper or that it would prevent a speaker from making a presentation, but rather to provide participants with information with which they can make their own judgments.

- This disclosure information will be provided as a statement in the program materials or will be verbally announced at the CE activity, followed by written documentation that the announcement was made.

- Any discussion by faculty of off-label use of drug products must be disclosed.

F. Grievance Policy

- If there is a grievance of any nature related to CE programs, the participants should contact the APA, Office of Training and Development (OTCOM), Division of Training and Development (DTD). The APA will meet with the complainants and seek to resolve the grievances to the satisfaction of all parties. Any unresolved grievances will be taken to the Director, DTD, for resolution.

- CDER will be accountable for any complaint or inquiry received up to 12 months after the date of the activity.

G. Privacy and Confidentially

- FDA and CDER do not disclose, give, sell, or transfer any personal information about participants, unless required for law enforcement or by statute. We will use personally

identifying information only to respond to participants, issue CE certificates, or share, if required, with the pharmacy and medical accreditation organizations (ACPE, ACCME) for the purpose of program completion verification.

- For Internet activities, the only tracking allowed will be information that indicates that a given individual took a quiz on a given date with a particular score. At the end of the session when the browser is closed, the tracking information will be removed from the Internet.

PROCEDURES

- Individuals or organizations interested in accreditation of an educational or training activity for CE credit should contact the Division of Training and Development (DTD), Office of Training and Communications (OTCOM), during the initial planning of the activity. The Accreditation Program Manager (APM) will provide guidance and assistance through the accreditation process and completion of the Accreditation Request Form (Attachment A).

- After review by the APM, the Accreditation Request Form is submitted to the CASE for an assessment of the scientific or regulatory merit of the content and proposed faculty.

- After review of the activity, the CASE will submit its recommendation to the APA for approval or disapproval of the proposed activity for CME and/or CPE credit.

RESPONSIBILITIES

The APA will:

- Approve and designate CE activities for CME and/or CPE accreditation.
- Ensure compliance with CDER's accreditation policies and procedures.
- Use the CASE to assess the scientific merit of the content and the proposed faculty.
- Maintain in an activity file all documents supporting the need, design, development, evaluation, and administration of an accredited activity. The activity file will be retained for the current accreditation period or the last 12 months, whichever is longer.
- Issue and keep a record of credit for participants of accredited CE activities for 6 years from the completion date of the activity.
- Review the accreditation program to ascertain whether the mission of the CE program is being achieved.

The APM will:

- Provide administrative management to the accreditation program.
- Maintain records and issue CE certificates of credit.
- Advise applicants in the completion of the Accreditation Request Form.
- Forward the completed Accreditation Request Form to CASE for review.
- Act in the absence of the APA.

The CASE will:

- Assess the content of the proposed activity for scientific merit and relevance to the mission of CDER.
- Assess the qualifications of the faculty.
- Recommend an activity for CME and/or CPE.
- Identify CE needs for physicians and pharmacists.

The Director, Division of Training and Development, will:

- Ensure continuity of the Accreditation Program by selecting the APA.
- Decide any unresolved grievances.

The Team Leader, Continuing Education and Professional Development, DTD, will:

- Act as the APA with responsibility for the direction and management of the accreditation program.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment: A

Accreditation Request Form
Center for Drug Evaluation and Research
Continuing Medical Education (CME) and
Continuing Pharmaceutical Education (CPE)

Division of Training and Development Use only
__ Directly sponsored
__ Jointly sponsored ACCME activity (CDER and non-accredited ACCME institution)
__ Co-sponsored ACCME activity (CDER and ACCME accredited institution)
__ Co-sponsored with non-ACPE approved provider
__ Co-sponsored with other ACPE approved provider
__ Journal Club
__ Course/workshop
__ Regularly scheduled conference
__ Live Internet
__ Enduring material/Home study
__ Enduring material/Internet

See Attachment B – Instructions for Completing the Accreditation Request Form

ACTIVITY DETAILS

Title:
Date(s) :
Time(s):
Number of continuing education hours requested: (50–60 minutes equals 1 instructional hour)
Target Audience: **Percentage of anticipated audience** M.D.s _____ Pharmacists _____Other Disciplines _____
Prerequisites:
Course Organizer(s): (organization name, phone, and location,) **Planning Committee** – please attach a list of members
DTD Project Manager:

Attachment A (continued)

FOR JOINTLY SPONSORED ACTIVITIES ONLY

Sponsoring Organization #1
(Name, address, phone, and FAX)
•
•
•
Sponsoring Organization #2
(Name, address, phone, and FAX)
•
•
•
Sponsorship Agreement – Attach Letter of Agreement (responsibilities and conditions of joint sponsorship)

PLANNING AND DEVELOPMENT

Method of Need Identification: (Attach Documentation)

___ Survey of target audience ___ Consensus of exerts
___ Training deficit ___ New policy
___ New techniques ___ Previous evaluations
___ Other (specify) _____

How will this activity fulfill the need?
_____
_____
_____

Goal: What is the overall goal of this activity?
_____
_____
_____
_____

Learning Objectives: Statement that reflects what each participant will learn by attending this program or activity. "At the conclusion of this activity, the participant will be able to do the following:"

1. _____

2. _____

3. _____

Attachment A (continued)

Instructional Method: Check all that apply.

__ Lecture __ Case study

__ Practice session __ Informal discussion

__ Small group discussion __ Demonstration

___ Other (specify) _____

How will the selected instructional method(s) achieve the learning objectives?

_____
_____
_____
_____
_____

Attach copy of outline/abstract of the content to be presented.

Delivery Method:

___ Computer based instruction ___ Internet

___ Live instructor led ___ Videoconference

___ Satellite broadcast ___ Self-study

___ Other (specify) _____

_____

EVALUATION

Evaluation Method: How will this educational activity be evaluated to see that it met its objectives? **(Attach a copy of the evaluation)**

_____
_____
_____

___ Questionnaire ___ Pre-post test

___ Group discussion ___ Follow-up survey

___ Case Study

___ Other (specify) _____

Attachment A (continued)

FACULTY

Faculty Information: Please attach the following information for each faculty member:

Name, affiliation, mailing address, phone, FAX, e-mail address, recent CV, faculty disclosure form (**Attachment D).**

Will off-label use be discussed? ___ No ___ Yes

What methods of disclosure will be used?

__ Will be on printed materials

__ Will be announced at start of program, activity or session

__ Will be posted via sign, slide, overhead

__ Other (specify) _____

Identify Faculty members seeking Category I AMA/PRA CME credit
(Attach list of names)

APPROVAL ACTION

Date submitted for review: _____

Recommended for _____ hours Category 1 continuing medical education credit (CME)
Recommended for _____ contact hours continuing pharmaceutical education credit (CPE).

Not recommended for CME and/or CPE for the following reasons:

_____
_____
_____

_____ _____
Chair, Committee for Advanced Scientific Education, CDER Date

Approved for _____ hours Category I continuing medical education (CME) credit.
Approved for _____ contact hours continuing pharmaceutical education (CPE) credit

_____ _____
Accreditation Program Administrator, CDER Date

Attachment A (continued)

- Letter of Agreement (for jointly sponsored activities)
- Method of Need Identification
- Evaluation Method
- Faculty Information

Attachment: B

Instructions for Completing the Accreditation Request Form

Activity Details

Provide the following information.

- **Title:** The name of the course, workshop, or program
- **Date:** The date the activity will take place
- **Time(s):** The day of the week and time of day activity will take place
- **Number of continuing education hours requested:** Calculate the hours of instruction for the activity. One instructional hour equals 50-60 minutes of instruction or its equivalent (no partial hours). The introductions, break time, and lunchtime should not be included in the calculation.
- **Target audience:** The individuals for whom the activity is intended. Please estimate the percentage of physicians, pharmacists, and other public health professionals you expect to attend.
- **Prerequisites:** Prior knowledge needed to successfully complete the planned activity.
- **Course Organizer:** The CDER staff person responsible for the development of the activity.
- **DTD Project Manager:** The DTD employee designated as the project manager for the activity.

For Jointly Sponsored Activities Only:

- **Sponsoring Organization:** Any institutions other than CDER involved in the development of an activity. If other organizations are involved, co-sponsorship agreements and/or commercial agreements are required. Information on co-sponsorship agreements is available from the FDA Ethics Branch.
- **Sponsorship Agreement:** Letter of agreement outlining responsibilities and conditions of joint sponsorship, to include a detailed description of funding.

Planning and Development:

- **Method of Need Identification:** Describe the educational and/or training need and the methods used to identify it. The need can be thought of as the difference between what is happening now in practice and what is expected. It is used to develop the learning objectives.

(If applicable, attach supporting documents such as meeting minutes, survey, or questionnaire)

- **Goal:** A general statement about the purpose of the activity and what you expect it to accomplish.

- **Learning Objectives:** The goal of the educational activity. The learning objectives tell the audience what they will gain by participating in the activity.

- **Instructional Methods:** The method of presentation for the activity.

- **Delivery methods:** How the content will be presented. Select delivery methods that are consistent with the learning objectives and instructional methods.

- **Method of Evaluation:** How you will know whether the activity achieved the objectives or was of value. Attach a copy of all evaluation forms to be used for this activity. The educational objectives must be stated on the evaluation form.

- **Faculty Information:** Disclosure Statements – Each non-CDER instructor is requested to complete the Faculty Disclosure Form (Attachment D) and indicate whether off-label use will be discussed. The standards for commercial support require that speakers involved in CME and CPE presentations disclose any economic or other personal interests that create, or may be perceived as creating, a conflict related to the presentation. The intent of this policy is not to prevent a speaker with a conflict of interest from making a presentation. The intent is that any conflict should be identified openly, with full disclosure of the facts, so that the listeners may form their own judgments about the presentation.

- **Identify Faculty Members Seeking Category I AMA/PRA Credit.** CDER, as an approved provider, may now award up to 2 Category 1 CME credits for every 1 hour of lecture up to a maximum of 10 hours per year. The learning activity must be designed for Category 1 CME. A copy of the course or seminar announcement listing the faculty member will be accepted as proof of participation. Submit the CE credit request form with each instructor's curriculum vitae.

Attachment: C

Determination of Credit for an Enduring Material

MERGENER[1] FORMULA WORKSHEET

Title of Program: _____

Universal Program Number: _____

Amount of credit assigned by the Provider: _____

Please insert numbers from your Mergener Formula calculations:

[-22.3 + (0.00209 x _____) + (2.78 x _____) +
number of words* number of questions

(15.5 x _____)] x 0.9 = _____
difficulty of the material** minutes

* Exclusive of tables/charts

** Depends on the target audience: Very easy = 1; Somewhat easy = 2; Moderate = 3; Difficult = 4; Very difficult = 5

[1] Mergener, MA, "A Preliminary Study to Determine the Amount of Continuing Education Credit to Award for Home Study Programs," *American Journal of Pharmaceutical Education*, Vol. 55, Fall 1991 (263-266).

Attachment: D

Faculty Disclosure Form

All faculty members participating in an accredited activity are expected to disclose any significant financial interest or other relationships (1) with the manufacturers of any commercial products to be discussed in the activity, and (2) with any commercial supporters of the activity, (i.e., grants, research support, honoraria, employee, consultant, stockholder).

Title of Activity/Presentation: _____

Date of Activity: _____

Presenter/Faculty Name: (printed) _____

Section I

Will your presentation include discussion of any commercial product or services?
_____ yes _____ no (if no, skip to Section II)

If yes, do you have a significant financial interest or other relationship with the manufacturers of any of the products or providers of any of the services you intend to discuss?
_____ yes _____ no

If yes, please list the manufacturers or providers and describe the nature of the relationships.

Section II

Is this activity supported by a grant from a commercial source? _____ yes _____ no (if no, skip to Section III)

If yes, please list the relevant commercial supporters and describe the nature of the relationship.

Do you have a significant relationship with the commercial supporters of this activity?

_____ yes _____ no

If yes, please list the relevant commercial supporters and describe the nature of the relationship.

Section III

Will your presentation include discussion of any unlabeled/investigational use of a commercial product?
_____ yes _____ no
If yes, please state the product and the use to be discussed.

Signature and Date: _____