OFFICE OF TRAINING AND COMMUNICATIONS

Accreditation — Continuing Education

CONTENTS

PURPOSE

- This MAPP describes the policies, procedures, and responsibilities for the accreditation of the education and training activities conducted by the Center for Drug Evaluation and Research (CDER). These procedures are intended to ensure that all education and training activities offered for continuing medical education credit (CME), continuing nursing education credit (CNE), and/or continuing pharmacy education credit (CPE) meet the standards and criteria for quality established by the Accreditation Council for Continuing Medical Education (ACCME), the Maryland Nurses Association (MNA)/American Nurses Credentialing Center (ANCC), and the Accreditation Council for Pharmacy Education (ACPE). This replaces MAPP 4550.2, Staff College.

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 pharmacy education (CPE) by the Accreditation Council for Pharmacy Education (ACPE). CDER is also an approved provider of continuing nursing education (CNE) by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

MISSION STATEMENT

- CDER's continuing education program supports and assists physicians, nurses, 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.

Goal

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

- Providing 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.

Scope

The work of CDER includes the review of investigational drug applications, new drug applications, abbreviated new drug applications (generic equivalents), postmarketing epidemiological studies that are submitted to the Food and Drug Administration, and issues related to compliance with drug regulatory law and postmarketing surveillance. The scope of the activities presented includes providing drug evaluation-related knowledge and skills, policy training, and scientific education related to drug development, drug evaluation, and postmarketing drug oversight. Through these activities CDER engages in joint sponsorship with organizations that share CDER's mission or educational objectives. Our delivery methods include traditional live instructor-led, computer-based, and web-based instructional formats.

Audience

The primary audience is made up of physicians, nurses, pharmacists, and scientists involved in drug evaluation science. A secondary audience includes health care professionals who have a need for knowledge in this area.

Activities

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

REFERENCES

- The ACCME's Accreditation Handbook
- The ACCME's Standard for Commercial Support
- The ACPE's Continuing Education Manual: Criteria for Quality and Interpretive Guidelines
- The Alliance for Continuing Medical Education Handbook
- Committee for Advanced Scientific Education By Laws, October 1998, amended June 2005
- Final Guidance on Industry-Supported Scientific and Educational Activities (62 FR 64093; December 3, 1999)
- FDA/CDER Policy and Procedures Manual for Provider Directed Activities (nurses), July 25, 2005

DEFINITIONS

Accreditation: The status conferred by an accrediting body such as the Accreditation Council for Continuing Medical Education (ACCME), the Maryland Nurses Association (MNA), or the Accreditation Council for Pharmacy Education (ACPE) to an entity that can meet specific quality criteria that are indicative of the organization's capability to develop and deliver 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 used by physicians in their maintenance of competence and incorporation of new knowledge to improve quality medical care for patients and their communities.

Accreditation Council for Pharmacy Education (ACPE): The not-for-profit agency responsible for the identification, development, and promotion of standards for quality continuing pharmacy education used by pharmacists that are judged to meet the ACPE's Criteria for Quality and Interpretive Guidelines. The ACPE's Accreditation Provider Program is designed to assure 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 responsible for the direction of the accreditation program; the individual authorized to approve an educational activity for continuing medical education, continuing nursing education, and/or continuing pharmacy education credit. The APA identifies and uses internal and external advisors to accomplish the mission of the accreditation program.

Accreditation Program Manager (APM): The individual responsible for the administrative management of the accreditation program. This includes maintenance of files and records, and the issuance of CE statements of credit.

Accreditation Request Form (ARF): The form used to document the planning, evaluation, and review of an educational activity for accreditation.

Activity: A single continuing education event, such as a seminar, rounds, or a course.

American Nurses Credentialing Center: A separately incorporated subsidiary of the American Nurses Association (ANA) that administers the credentialing programs of ANA, including both accreditation and certification. The credentialing programs are based on ANA's standards for nursing education, nursing practice, and nursing service.

CDER Nurses Network Education Subcommittee (CNNES): The subcommittee responsible for identifying topics of interest to assist nurses and other scientific staff within FDA/CDER in maintaining the highest degree of professional competence by presenting "cutting edge" information to improve patient safety and drug products. This committee also reviews proposed continuing nursing education activities in terms of scientific merit, possible conflict of interest, and faculty qualifications.

Committee for Advanced Scientific Education (CASE): The principal scientific educational advisory committee for CDER. The CASE mission is to promote excellence in advanced scientific education and assist CDER's scientific personnel to maintain currency and a high level of competency in the advanced regulatory and scientific knowledge of drug evaluation, to meet the complex challenges of evolving and innovative drug development in a global environment.

Continuing Medical Education (CME): Activities that help 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 Nursing Education (CNE): Systematic professional learning experiences designed to augment the knowledge, skills, and attitudes of nurses and, therefore, enrich nurses' contributions to quality health care and their pursuits of professional career goals.

Continuing Pharmacy Education (CPE): A structured educational activity designed or intended to support the continuing development of pharmacists and/or pharmacy technicians to maintain and enhance their competence. Continuing pharmacy education (CPE) should promote problem-solving and critical thinking and be applicable to the practice of pharmacy.

Continuing Education Program: Any form of educational experience that supports continued learning, targets an audience of physicians, nurses, pharmacists, and/or other public health professionals, and is consistent with the definitions of CME, CNE, and CPE, respectively.

Educational Design Form (EDF): The form used to document the design and development of an educational activity to include objectives, content outline, instructional method and materials, learning activity, faculty, and time allotment.

Nurse Planner: A registered nurse who is responsible for planning, developing, implementing, and evaluating continuing education activities. For an approved provider, the "Nurse Planner" must have a baccalaureate or higher degree in nursing.

Sponsorship: A comprehensive term implying a state of responsibility of the organization accredited for its overall continuing education program. This state applies to the accredited provider, who is expected to be integrally involved and who has the responsibility for the determination of needs, planning, design, promotion, implementation, evaluation, and certification of a course, as well as the financial responsibility. The sponsor designates credit.

Joint Sponsorship: An arrangement in which an accredited sponsor becomes a joint sponsor and lends its accreditation status to a non-accredited entity. The accredited sponsor bears the same responsibility as a sole sponsor. All sponsorship criteria apply.

PROCEDURES

1. Individuals or organizations interested in accreditation of an educational or training activity for CME, CNE, and/or CPE credit should contact an Accreditation Program Manager (APM) in the Division of Training and Development (DTD), Office of Training and Communications (OTCOM), during the initial planning of the activity. The APM will provide guidance and assistance on completion of the Accreditation Request Form (ARF) (Attachment A), and any other necessary guidance throughout the accreditation process.

2. After review by the APM, the ARF is submitted to the CASE and/or the CNNES for an assessment of the scientific or regulatory merit of the content and proposed faculty to present it.

3. After review of the activity, CASE and/or CNNES will submit its recommendation to the Accreditation Program Administrator (APA) for approval/disapproval of the proposed activity for CME, CPE, and/or CNE credit.

POLICY

A. General

1. The Educational Design Form (EDF) (Attachment B) must be used in planning and developing all activities. The ARF must be used in the review and approval for all continuing education activities seeking CME, CNE, and/or CPE.

2. CDER will document the processes used to identify the continuing education needs of the participants and indicate how these needs will be met by the training or education activity. Learning objectives and a learning activity for the expected learning outcomes are required for each continuing education activity. Each activity will be evaluated after the event to determine whether it met the training need identified.

3. CDER will ensure balance, independence, objectivity, and scientific rigor in all directly sponsored or jointly sponsored educational activities.

4. Continuing education activities requesting CPE must be submitted at least 60 days before the event.

5. An activity seeking accreditation will not be advertised or promoted for CME, CNE, and/or CPE until the APA has approved it.

B. Commercial Support

When commercial support (funding or resources) is accepted from another organization, CDER will adhere to the following.

1. CDER must ensure that the following criteria are met.

   - The activity is free of commercial bias for or against any product.
   - Activities related to commercial products must 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 reference material must remain the responsibility of CDER. None of the materials may advance the proprietary interests of the commercial supporter.
   - CDER may seek assistance from an outside source; however, acceptance of advice about speakers, content, or other educational matters will not be a condition of support.
   - 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 having been developed by CDER.

- When CDER offers an activity prepared by proprietary entities, that activity must adhere to all ACCME, MNA/ANCC, and ACPE standards.

3. When 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. If trade names are used, those of several companies, rather than that of a single supporting company, should be used.
   - Require commercial entities presenting scientific research to provide CDER with documentation to confirm the scientific objectivity of the presentation and ensure conformance with accepted standards of experimental design, data collection, and analysis.

4. CDER will be 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 documented. This agreement will describe the purposes, terms, and conditions of the joint sponsorship or co-sponsorship arrangement. In addition, the agreement will specifically address the following:

   - CDER's responsibility for the content, quality, and scientific integrity of this CE activity.
   - Acknowledgement of funds received from the commercial supporter and earmarked for a specific CE activity. Any funds received in this manner will require a separate signed written agreement with that funding entity.
   - The roles and responsibilities of each sponsor in the implementation and delivery of the activity.

5. Exhibits and other commercial activities may not influence or interfere with a CE activity. No commercial promotional materials may be displayed or distributed in the same room immediately before, during, or immediately after an activity for CE. CDER will not allow representatives of commercial supporters to engage in sales and promotional activities in the same place as a CE activity.

C. Determination of Credit

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

2. For enduring materials/home study programs and other mediated instructional activities, the amount of educational credit will be determined by pilot testing or using the Mergener Formula (see Attachment C — Determination of Credit for an Enduring Material).

3. The number of instructional hours to be awarded for participation and the criteria for successful completion of an accredited continuing education activity will be determined and made known by CDER in advance of offering the activity.

D. Enduring Materials

Enduring materials are 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.

1. CDER is responsible for the quality, content, and use of the enduring material/home study programs.

2. CDER will ensure commercial acknowledgement in enduring materials/home study programs through the following:
   - Product-specific advertising of any type is prohibited in enduring materials.
   - Commercial support must be acknowledged.
   - This acknowledgement must be placed at the beginning of the enduring material.
   - The 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 are not product-promotional in nature.

3. No specific products may be referenced, even if they are not related to the topic of the enduring material.

4. Enduring materials/home study programs must communicate the following information to participants:
   - Principal faculty and their credentials
   - Medium or combination of media used
   - Estimated time to complete the educational activity
   - The number of designated credit and/or contact hours
   - Termination date
   - Criteria for earning credit, and how to obtain a statement of credit
   - Dates of original release and most recent review or update
   - Disclosure
   - Learning Objectives
   - Fees/refund information
   - Appropriate accreditation statements with trademarks if applicable
   - Title of activity
   - Purpose of activity or brief description
   - For Internet provided instructions:
     - The software and hardware needed to participate
     - The method for contacting CDER if participants have questions about the Internet activity
     - CDER's policy on privacy and confidentiality for CME, CNE, and/or CPE activities it provides on the Internet
     - Documentation of compliance with copyright law, if applicable

E. Faculty Disclosure and Conflict of Interest

1. CDER must demonstrate that everyone who is in a position to control the content of an educational activity has disclosed all relevant economic and or personal interests that create, or may be perceived as creating a conflict related to the presentation.

2. 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 disclosure should include the name of the individual, the name of the commercial interest(s), and the nature of the relationship the person has with each commercial interest.

3. An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, presenter, or author of CE. This individual cannot have control of, or responsibility for the development, management, presentation, or evaluation of the CE activity. NOTE: ACCME defines "relevant" financial relationships as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

4. This disclosure information will be provided as a statement in the program materials, and/or a statement that will be announced verbally before the beginning of the educational activity, followed by written documentation that the announcement was made.

5. Any discussion of off-label or investigational use of drug products must be disclosed.

6. CDER must implement a mechanism to identify and resolve all conflicts of interest prior to the educational activity.

F. Grievance Policy

1. Should any participants find grievance of any nature related to the continuing education programs, the participants should contact the APA. 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 of DTD for resolution.

2. CDER will be accountable for any complaint or inquiries received up to 12 months from the date of the activity.

G. Privacy and Confidentiality

FDA/CDER does not disclose, give, sell, or transfer any personal information about our participants, unless required for law enforcement or by statute. We will only use personally identifying information to respond to you, issue statements of credit, or share, if required, with the pharmacy, nursing, and medical accreditation organizations (ACPE, MNA/ANCC, and ACCME) for the purpose of program completion verification.

For Internet activities, the only cookies used are session cookies, which allow tracking that a given individual took the quiz on a given date with a particular score. At the end of the session, when the browser is closed, the cookie is deleted.

RESPONSIBILITIES

1. The Accreditation Program Administrator (APA) will:

- Approve and designate a continuing education activity for CME, CNE, and/or CPE accreditation.
- Ensure compliance with CDER's accreditation policies and procedures.
- Use the CASE and/or CNNES to assess the scientific merit of the content to be presented and the faculty proposed for presenting the content.
- Review the accreditation program to ascertain the extent to which the mission of the continuing education program is being achieved.

2. The Accreditation Program Manager (APM) will:

- Provide administrative management to the accreditation program.
- Maintain all documents supporting the need, design, development, evaluation, and administration of an accredited activity in an activity file for 6 years.
- Issue and keep a record of credit for participants of accredited continuing education activities for 6 years from the completion date of the activity.
- Advise and guide applicants in the completion of the ARF.
- Forward the completed ARF to CASE and/or CNNES for review.
- Act in the absence of the APA.

3. The Committee for Advanced Scientific Education **(**CASE) and the CDER Nurses Network Education Subcommittee (CNNES) will:

- Serve as the peer review body to ensure content validity and content alignment with the interest of the participants.
- Assess the content of the proposed activity for its scientific merit and relevancy to the mission of CDER.
- Assess qualifications of faculty to present the content.
- Recommend an activity for CME, CPE, and/or CNE.
- Identify continuing education needs for physicians, pharmacists, and nurses.

4. The Director, Division of Training and Development will:

- Ensure continuity of the accreditation program by selecting the APA.
- Settle any unresolved grievances.

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)
Continuing Pharmacy Education (CPE)
Continuing Nursing Education (CNE)

Division of Training and Development Use only
__ Directly sponsored
__ Jointly sponsored
__ Journal club
__ Live activity
__ Regularly scheduled conference
__ Live Internet
__ Enduring material/home study

ACTIVITY DETAILS
Application Date_____ Expiration Date_____

Title:

Date(s) :

Time(s):

Type and number of continuing education hours requested: CME ___CPE___CNE___
(60 minutes equals one instructional hour)

Target Audience:

Percentage of anticipated audience:

Physicians _____ Pharmacists _____ Nurses _____Other Disciplines _____

Prerequisites:

Organizer(s):
(name, phone and location, organization)

Planning Committee – please attach a list of members

DTD Program 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

Attach required supporting documentation listed and answer the following questions.

____Educational Design Form
____Method of Need Identification
____Learning Activity
____Final Activity Evaluation form (and lecture evaluation if applicable)
____Outline
____Faculty Information
____Planning meeting minutes (if available)
____Planning Committee Disclosure Forms

Method of Need Identification (Attach Documentation)

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

How will this activity fulfill the need?

_____
_____
_____

Goal: What is the overall goal of this activity?

_____
_____
_____
_____

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

_____
_____
_____
_____

Learning Activity Method (Attach Documentation)

___ Challenge Questions
___ Structured group discussion
___ Case Study
___ Pre-post test
___ Audience Response System
___ 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.

Will off label use be discussed? ___ No ___ Yes

What methods of disclosure will be used? (Minimum of one required – two recommended)

__ Will put on printed materials
__ Will announce at start of activity (Written verification required)
__ Will post 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 pharmacy education credit (CPE).

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

_____
_____
_____

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

Recommended for_____contact hours continuing nursing education credit (CNE).

Not recommended for CNE for the following reasons:

_____
_____
_____

_____ _____
Nurse Planner, CDER **Date**

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

_____ _____
Accreditation Program Administrator, CDER **Date**

Attachment A (continued)

Instructions for Completing the Accreditation Request Form

Activity Details: Provide the following information for the items listed.

- **Title:** The name of the activity.
- **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:** Organized and structured instruction is defined as the content that is presented related to the learning objectives for the activity. Evaluation and learning activities are also considered in the overall determination of credit. An instructional hour will consist of 60 minutes for CME, CPE, and CNE in an organized continuing education activity. For live programs, CDER will total the number of actual organized instructional hours from the final agenda of an activity, not to include registration, breaks, or lunches.
- **Target audience:** The individuals that the activity is directed towards. Please estimate the percentage of physicians, pharmacists, nurses, and other public health professionals you expect to attend.
- **Prerequisites:** Prior knowledge needed to successfully complete the planned activity.
- **Organizer:** The CDER staff person(s) responsible for the development of the activity.
- **DTD Program Manager:** The DTD employee designed as the program manager for the activity.

For Jointly Sponsored Activities Only:

- **Sponsoring Organization:** Institution(s) other than CDER involved in the development of an activity. 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, including a detailed description of funding (attached).

Planning and Development:

- **Method of Need Identification:** Describe the educational and/or training need and the method(s) 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, surveys, or questionnaires.)

Attachment A (continued)

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

- **Learning Objectives:** Learning objectives are statements that communicate the intent of the educational activity. Objectives are action statements that operationalize a goal. They tell the audience what they will gain by participating in the activity.

- **Instructional Methods:** The instructional method to be used to present the content of activity; the best methods to deliver content and achieve the objectives.

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

- **Learning Activity:** Any activity that would allow for the evaluation of the effectiveness of the activity to meet the identified (educational) need and allow participants to determine their understanding of the content presented.

Faculty:

- **Final Activity Evaluation:** The method of evaluation that will let you know if the activity achieved what you wanted it to 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:** The Standards for Commercial Support require that speakers involved in CME, CPE, and CNE presentations disclose any economic or other personal interests that create, or may be perceived as creating a conflict related to the presentation. Any speaker refusing to disclose will be disqualified from being a presenter of a CE activity. This policy ensures that conflicts of interest are openly identified and resolved prior to the educational activity.

- **Identify Faculty members seeking Category I AMA/PRA credit:** As an approved provider, CDER may now award up to two 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 activity announcement will be accepted as proof of participation. Submit the CE credit request form with each instructor's curriculum vitae.

Attachment B

EDUCATIONAL DESIGN FORM

Title of Activity: **<Insert Title Here>**

Behavioral Objectives	Content Outline	Instructional Methods	Learning Activity	Instructional Materials	Faculty	Time Frame
(By the completion of the activity, what skills, training, or education will the participants acquire?)	Main topic Subtopic Another subtopic Another subtopic	Lecture Group Discussion	Audience Response Challenge Questions Case Study	Textbook Handbook Handouts	Name of presenter	XX min

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).