(5) **Calculation of mean absorbance values.** (i) Mean transmittance values, 
\[ T(\lambda), \]
are converted into mean absorbance values, 
\[ A(\lambda), \]
at each wavelength by taking the negative logarithm of the mean transmittance value as follows:
\[ A(\lambda) = -\log T(\lambda) \]
(ii) The calculation yields 111 monochromatic absorbance values in 1 nanometer increments from 290 to 400 nanometers.

(6) **Number of plates.** For each sunscreen product, mean absorbance values should be determined from at least three individual PMMA plates. Because paragraph (d) of this section requires at least 5 measurements per plate, there should be a total of at least 15 measurements.

(7) **Calculation of the critical wavelength.** The critical wavelength is identified as the wavelength at which the integral of the spectral absorbance curve reaches 90 percent of the integral over the UV spectrum from 290 to 400 nm. The following equation defines the critical wavelength:
\[ \int_{290}^{400} A(\lambda)d\lambda = 0.9 \int_{290}^{400} A(\lambda)d\lambda \]
Where \(\lambda_c\) = critical wavelength
\[ A(\lambda) = \text{mean absorbance at each wavelength} \]
\[ d\lambda = \text{wavelength interval between measurements} \]
A mean critical wavelength of 370 nm or greater is classified as broad spectrum protection.

[76 FR 35660, June 17, 2011, as amended at 76 FR 38975, July 5, 2011]

**EFFECTIVE DATE NOTE:** At 76 FR 35660, June 17, 2011, §201.327 was added, effective June 18, 2012.

**APPENDIX A TO PART 201—EXAMPLES OF GRAPHIC ENHANCEMENTS USED BY FDA**

**I. SECTION 201.66 STANDARD LABELING FORMAT**

**A. Overall**

1. The “Drug Facts” labeling is set off in a box or similar enclosure by the use of a barline with all black type printed on a white, color contrasting background.

**B. Typeface and size**

1. “Drug Facts” is set in 14 point Helvetica Bold Italic, left justified.
2. “Drug Facts (continued)” is set in 8 point Helvetica Bold Italic for the words “Drug Facts” and 8 point Helvetica Regular for the word “(continued)” and is left justified.
3. The headings (e.g., “Directions”) are set in 8 point Helvetica Bold Italic, left justified.
4. The subheadings (e.g., “Ask a doctor or pharmacist before use if you are”) are set in 6 point Helvetica Bold, left justified.
5. The information is set in 6 point Helvetica Regular with 6.5 point leading, left justified.
6. The bullet is a 5-point solid square.
7. Two em spacing separates bullets when more than one bullet is on the same line.
8. A table format is used for 3 or more dosage directions.
9. A graphic appears at the bottom of the first panel leading the reader to the next panel.

**C. Barlines and hairlines**

1. A 2.5-point horizontal barline extends to each end of the “Drug Facts” box (or similar enclosure), providing separation between each of the headings.
2. A 0.5-point horizontal hairline extends within 2 spaces on either side of the “Drug Facts” box (or similar enclosure), immediately following the title and immediately preceding the subheadings.
3. A 0.5-point horizontal hairline follows the title, immediately preceding the heading, when a heading appears on a subsequent panel immediately after the “Drug Facts (continued)” title.

**D. Box or Enclosure**

1. All information is enclosed by a 2.5-point barline.

**II. SECTION 201.66 MODIFIED LABELING FORMAT**

**A. Overall**

1. The “Drug Facts” labeling is presented in all black type printed on a white color contrasting background.
II. EXAMPLES OF § 201.66 STANDARD LABELING AND MODIFIED LABELING FORMATS

A. SECTION 201.66 STANDARD LABELING FORMAT

B. Typeface and Size

1. “Drug Facts” is set in 9 point Helvetica Bold Italic, left justified.
2. The headings (e.g., “Directions”) are set in 8 point Helvetica Bold Italic, left justified.
3. The subheadings (e.g., “Ask a doctor or pharmacist before use if you are”) are set in 6 point Helvetica Bold, left justified.
4. The information is set in 6 point Helvetica Regular with 6.5 point leading, left justified.
5. The heading “Purpose” is right justified.
6. The bullet is a 5-point solid square.
7. Bulleted information may start on same line as headings (except for the “Warnings” heading) and subheadings, with 2 em spacing separating bullets, and need not be vertically aligned.

C. Barlines and Hairlines

1. A 2.5-point horizontal barline extends to each end of the “Drug Facts” box (or similar enclosure), providing separation between each of the headings.
2. A 0.5-point horizontal hairline extends within 2 spaces on either side of the “Drug Facts” box (or similar enclosure), immediately following the title and immediately preceding the subheadings.

D. Box or Enclosure

1. All information is set off by color contrast. No barline is used.

Title:
14 pt. Helvetica Bold Italic, left justified

Body text:
6 pt. Helvetica Regular with 6.5 pt. leading, left justified

Subheadings:
6 pt. Helvetica Bold, left justified

Bullet:
5 pt. Solid square

Headings:
8 pt. Helvetica Bold Italic, left justified

Title for continued panel:
8 pt. Helvetica Bold Italic
Title: Food and Drug Administration, HHS

§ 202.1 Prescription-drug advertisements.

(a)(1) The ingredient information required by section 502(n) of the Federal Food, Drug, and Cosmetic Act shall appear together, without any intervening written, printed, or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names.

(2) The order of listing of ingredients in the advertisement shall be the same as the order of listing of ingredients on the label of the product, and the information presented in the advertisement concerning the quantity of each such ingredient shall be the same as the corresponding information on the label of the product.

(3) The advertisement shall not employ a fanciful proprietary name for the drug or any ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition, when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.

(4) The advertisement shall not feature inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.

(5) The advertisement shall not designate a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

(b)(1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation shall accompany such proprietary name or designation each time it is featured in the advertisement for the drug; but, except as provided below in this subparagraph, the established name need not be used with the proprietary name or designation in the running text of the advertisement. On any page of an advertisement in which the proprietary name or designation is not featured but is used in the running text, the established name shall be used at least once in the running text in association with such proprietary name or designation and in the same type size used in the running text: Provided, however, That if the proprietary