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Guidance for Industry

Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**June 2011
Compliance**

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1
2
3 **Guidance for Industry¹**
4 **Enforcement Policy –**
5 **OTC Sunscreen Drug Products Marketed Without an Approved**
6 **Application**

7 This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s) current
8 thinking on this topic. It does not create or confer any rights for or on any person and does not operate to
9 bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of
10 the applicable statutes and regulations.
11

12
13
14
15 **I. INTRODUCTION**

16
17 This guidance is intended for manufacturers who market over-the-counter (OTC) sunscreen drug
18 products without an approved application.² OTC sunscreens are not yet the subject of an
19 effective final monograph, and we continue to evaluate information relevant to defining
20 conditions under which such products are GRASE and not misbranded. However, OTC
21 sunscreens marketed without approved applications and containing specified active ingredients
22 (see section II of this guidance) are subject to a final rule issued in 2011 that establishes labeling
23 and testing requirements. Several other ongoing and planned rulemaking proceedings also
24 address these products. Because questions may arise about the agency’s expectations in light of
25 these various proceedings, this guidance document describes the Agency’s intended enforcement
26 approach with respect to OTC sunscreen products marketed without approved applications.
27

28 FDA’s guidance documents, including this guidance, do not establish legally enforceable
29 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
30 be viewed only as recommendations, unless specific regulatory or statutory requirements are
31 cited. The use of the word *should* in Agency guidances means that something is suggested or
32 recommended, but not required.
33

34 **II. BACKGROUND**

35
36 We have previously published a number of *Federal Register* notices pertaining to rulemaking
37 related to OTC sunscreen products. They can be found on our website:
38 <http://www.fda.gov/OTCRulemaking>. Rather than discuss all of the proceedings, we summarize
39 those that are most relevant to the enforcement policy described in this guidance.

¹ This guidance has been prepared by the Division of Nonprescription Regulation Development in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

² See section 505 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355). Approved applications under section 505 include both New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs). Some OTC sunscreen products are currently marketed under approved applications. This guidance document does not address those products.

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40
41 In 1978, we published an advance notice of proposed rulemaking (ANPR) that included
42 recommendations from an advisory review panel³ on the safe and effective use of OTC
43 sunscreen products (43 FR 38206). In the ANPR, we stated that the panel recommended 21
44 sunscreen active ingredients be determined as GRASE. The panel recommended all sunscreen
45 products have SPF values of 2 or higher. The panel also recommended a maximum labeled SPF
46 value of 15. The panel did not address broad spectrum protection,⁴ nor did the panel address
47 insect repellent-sunscreen combination products. The panel discussed OTC sunscreen products
48 formulated as oils, lotions, creams, gels, butters, pastes, sticks, ointments, and sprays, but did not
49 recommend classifying any specific dosage forms as GRASE.

50
51 In 1993, we published a proposed rule that included our proposed GRASE conditions for OTC
52 sunscreen products (58 FR 28194). We proposed as GRASE the same active ingredients
53 included in the ANPR except padimate A (i.e., 20 proposed GRASE ingredients). We proposed
54 a minimum SPF value of 2 as stated in the ANPR and proposed a maximum labeled SPF value of
55 30. We did not propose broad spectrum protection requirements or address insect repellent-
56 sunscreen combination products. In discussing proposed directions, we mentioned several
57 dosage forms, but did not expressly discuss what dosage forms of sunscreens were considered to
58 be GRASE and not misbranded. (See 58 FR 28243-44, 28297 (proposed 21 CFR 352.52(d)
59 (“(e.g., cream, gel, lotion, oil, spray, etc.).”)

60
61 We proposed two additional sunscreen active ingredients as GRASE after the 1993 proposed
62 rule. In 1996, we proposed adding avobenzone as a GRASE active ingredient (61 FR 48645). In
63 1998, we proposed adding zinc oxide as a GRASE active ingredient (63 FR 56584).

64
65 In 1999, we published a final rule that resolved most of the issues in the 1993, 1996, and 1998
66 proposed rules (64 FR 27666). The final rule established a sunscreen monograph in part 352
67 (21 CFR part 352) that had an effective date of May 21, 2001. We included as GRASE
68 conditions for sunscreens the following active ingredients with the following maximum
69 concentrations (See § 352.10, now stayed; 64 FR 27666 at 27687):⁵

- 70
71
- Aminobenzoic acid (PABA), 15 percent
 - 72 • Avobenzone, 3 percent
 - 73 • Cinoxate, 3 percent

³ The panel was a group of experts on sunscreens from outside FDA that we created to give us advice on developing an OTC sunscreen monograph.

⁴ Broad spectrum protection means protection against ultraviolet B (wavelengths of 290 to 320 nanometers) and ultraviolet A radiation (wavelengths of 320 to 400 nanometers).

⁵ The active ingredient names used in this list are the current established names for these active ingredients. Subsequent to the publication of the 1999 final rule, we issued another final rule in 2002 to amend the names used for four of those ingredients, to make them consistent with renaming of those ingredients in the corresponding USP monographs (67 FR 41823). Under section 502(e) of the FD&C Act, drug labels are required to bear the established name of the drug, and under section 508 of the FD&C Act, if the agency has not designated an official name, the compendial name is the established name. Consequently, to comply with section 502(e) of the Act, sunscreen drug products must bear the current compendial names for their active ingredients, and those are used in the text above. However, because the 2002 final rule that changed those names was published after the effective date of part 352 was stayed, those amendments have not yet been incorporated into the published monograph regulation.

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- 74 • Dioxybenzone, 3 percent
- 75 • Ensulizole, 4 percent⁶
- 76 • Homosalate, 15 percent
- 77 • Meradimate, 5 percent⁷
- 78 • Octinoxate, 7.5 percent⁸
- 79 • Octisalate, 5 percent⁹
- 80 • Octocrylene, 10 percent
- 81 • Oxybenzone, 6 percent
- 82 • Padimate O, 8 percent
- 83 • Sulisobenzene, 10 percent
- 84 • Titanium dioxide, 25 percent
- 85 • Trolamine salicylate, 12 percent
- 86 • Zinc Oxide, 24 percent

87

88 We concluded that these ingredients at these concentrations could also be used in combination as
89 long as each active ingredient contributes a minimum SPF of 2 to the finished product, except
90 that avobenzone may not be combined with aminobenzoic acid (PABA), menthyl anthranilate,
91 padimate O, titanium dioxide, and zinc oxide (See 21 CFR 352.20, now stayed; 64 FR 27666 at
92 27687-88). We identified the same dosage forms in the 1999 final rule as were included in the
93 ANPR and 1993 proposed rule (21 CFR 352.52(d) and 352.72(e)). We raised the maximum
94 labeled SPF value to 30. We did not propose broad spectrum protection requirements or address
95 insect repellent-sunscreen combination products.

96

97 In 2000, we delayed the effective date for the 1999 final rule until December 31, 2002 (65 FR
98 36319). In 2001, we stayed the December 31, 2002 effective date of the 1999 final rule
99 indefinitely (66 FR 67485). We delayed the effective date because we had not yet established
100 UVA/broad spectrum testing and labeling requirements for OTC sunscreen products. We
101 decided to include these requirements in the monograph before making it effective. Therefore,
102 there has never been an OTC drug monograph in effect for sunscreen products.

103

104 In 2007, we published an ANPR requesting information and comment on specific topics
105 including the effectiveness and safety of sunscreen products when combined with certain insect
106 repellent ingredients (72 FR 7941). The 2007 ANPR discussed five insect repellents then
107 registered by the Environmental Protection Agency (EPA), which regulates insect repellents
108 under the Federal Insecticide, Fungicide, and Rodenticide Act: N,N-diethyl-meta-toluamide
109 (DEET), oil of citronella, IR3535, p-menthane-3,8-diol, and picaridin. We stated that our
110 historical enforcement policy has allowed the marketing of insect repellent-sunscreen drug
111 products pending the establishment of an effective final sunscreen monograph, as long as the
112 products contained sunscreen ingredients included in the FDA OTC sunscreen rulemaking and
113 an insect repellent registered with EPA (72 FR 7941 at 7943). We stated that final regulations
114 for insect repellent-sunscreen products would be based on information and comments submitted

⁶ Referred to in the 1999 final rule as phenylbenzimidazole sulfonic acid. See footnote 6.

⁷ Referred to in the 1999 final rule as menthyl anthranilate. See footnote 6.

⁸ Referred to in the 1999 final rule as octyl methoxycinnamate. See footnote 6.

⁹ Referred to in the 1999 final rule as octyl salicylate. See footnote 6.

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115 in response to the 2007 ANPR. We have not published a proposed rule addressing insect
116 repellent-sunscreen products at this time.

117
118 In 2011, we published a final rule, codified in § 201.327, that established labeling and testing
119 requirements for OTC sunscreen products marketed without approved applications and
120 containing only the ingredients specified in the stayed 1999 final rule (see above). (INSERT FR
121 CITATION). For these “covered” products, the 2011 final rule:

- 122
- 123 • Established labeling for SPF and broad spectrum protection and specified test
 - 124 methods for establishing SPF values and broad spectrum protection
 - 125 • Established labeling and testing for water resistance
 - 126 • Addressed other elements of labeling, including directions for use and warnings
- 127

128 The final rule also identified specific claims that render a covered product misbranded or would
129 not be allowed on any OTC sunscreen product marketed without an approved application. (21
130 CFR 201.327(c)(3) and (g) and 310.545(a)(29)(ii)). The final rule addressed labeling and testing
131 comments raised in response to the 2007 sunscreen proposed rule, but did not address sunscreen
132 active ingredients or combination products that include sunscreen active ingredients.

133
134 In 2011, we also published a proposed rule to limit the maximum labeled SPF value for OTC
135 sunscreen products to “50+” [INSERT FR CITATION]. If the proposal were finalized, an OTC
136 sunscreen product marketed without an approved application and labeled with a specific SPF
137 value higher than 50 would be liable to regulatory action.

138
139 In 2011, we also published an ANPR requesting additional data on OTC sunscreen products in
140 certain dosage forms. We listed those dosage forms of OTC sunscreen products that we
141 currently considered potentially eligible for inclusion in the OTC sunscreen monograph (i.e.,
142 oils, lotions, creams, gels, butters, pastes, ointments, sticks, and sprays. For sprays, we requested
143 additional data to address remaining questions about effectiveness and safety. We also invited
144 comment on potential labeling and testing conditions for sunscreens in spray dosage forms,
145 contingent on receiving additional data that would be needed to allow their classification as
146 GRASE. We also identified certain dosage forms that we do not consider currently eligible for
147 review for potential inclusion in the OTC sunscreen monograph (i.e., wipes, towelettes, powders,
148 body washes, and shampoos).

149 **III. ENFORCEMENT POLICY**

150
151
152 Because there is no final OTC sunscreen monograph in effect, certain OTC sunscreen products
153 have been marketed under our enforcement discretion since the OTC monograph process was
154 established. We intend to continue to exercise enforcement discretion for certain OTC sunscreen
155 products under the circumstances described in this guidance. Sections III.A through D describe
156 the circumstances under which we intend to exercise enforcement discretion with respect to
157 certain OTC sunscreen products marketed without approved applications until a final OTC
158 sunscreen monograph becomes effective. Section III.E describes our approach to products
159 formulated in certain dosage forms, particularly sprays. Section III.F describes our approach to
160 products that contain both a sunscreen and an insect repellent, and section III.G describes

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161 sunscreen products that must comply with the requirements of 21 CFR 330.14(h) in order to be
162 marketed. Manufacturers should be certain to examine sections III.A through III.F to determine
163 if the conditions in more than one of these sections apply to a single sunscreen product. In such
164 a case, our enforcement policy is premised on adherence to all applicable recommendations.

165

A. General Enforcement Policy

166

167
168 Unless the failure to pursue regulatory action poses a potential health hazard to the
169 consumer, we do not intend to object to the marketing without an approved application of
170 OTC sunscreen products that have all of the following characteristics:

171

- 172 • Contain only the active ingredients or combinations of active ingredients
173 listed in Section II of this guidance (previously included in 21 CFR 352.10
174 and 352.20, which are now stayed),
- 175 • Do not make claims addressed in 21 CFR 201.327(c)(3) and (g) and
176 310.545(a)(29)(ii),
- 177 • Comply with the requirements for OTC drugs under 21 CFR part 201 and
178 330.1, requirements for adverse event reporting for OTC drugs, and
179 provisions of the FD&C Act addressing adulteration, and
- 180 • Follow labeling and testing requirements in § 201.327 (in accordance with the
181 effective date and compliance dates established in the 2011 final rule) except
182 as specific recommendations of this guidance address below.

183

184 It should be noted that cosmetic products labeled with sunscreen claims (e.g., including
185 an SPF value) are regulated as drugs¹⁰ and, therefore, covered by this enforcement policy.

186

B. Broad Spectrum Testing

187

188
189 The 2011 final rule includes an in vitro broad spectrum test procedure for assessing
190 protection across both UVA and UVB regions of the UV spectrum (See 21 CFR
191 201.327(j)). Certain elements of labeling in the 2011 final rule apply only to products
192 that are determined to be “Broad Spectrum” in accordance with this test procedure. FDA
193 is aware that not all sunscreen active ingredients provide substantial protection against
194 UVA wavelengths, and that OTC sunscreen products that do not contain certain
195 ingredients are not likely to pass the broad spectrum test criteria. FDA does not expect a
196 covered sunscreen to have been tested in accordance with 21 CFR 201.327(j) so long as it
197 does not bear any labeling that the final rule specifies as applicable only for products that
198 pass the broad spectrum test, or otherwise suggest that it provides broad spectrum
199 protection or helps to decrease the risk of skin cancer or premature skin aging.

200

201

¹⁰ See 21 CFR 700.35.

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202 **C. SPF Testing**

203
204 Among other provisions, the 2011 final rule requires that labeling for covered OTC
205 sunscreen products bear SPF values determined in accordance with the SPF testing
206 requirements in § 201.327(i). We expect covered OTC sunscreen products initially
207 marketed after [INSERT DATE OF PUBLICATION OF FINAL RULE] to conduct SPF
208 testing according to the method specified in § 201.327(i) and utilize this value in labeling
209 by the compliance dates indicated in the rule.¹¹ In response to the 2007 proposed rule, we
210 received submissions from sunscreen manufacturers requesting an implementation period
211 of 3 years to comply with the 2011 final rule. The manufacturers expressed concern that
212 testing laboratories would not have sufficient capacity to accommodate testing for all
213 sunscreen products covered by the rule if we required a shorter implementation period.
214 In light of this concern, we do not intend to initiate enforcement action before [INSERT
215 DATE 2 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE] for OTC
216 sunscreen products that:

- 217 • are subject to the 2011 final rule,
- 218 • were on the market prior to [INSERT DATE OF PUBLICATION OF FINAL
219 RULE], the date of publication of the final rule, and
- 220 • are labeled with an SPF value determined prior to [INSERT DATE OF
221 PUBLICATION OF FINAL RULE] using the SPF test method described in
222 the 1999 final rule (64 FR 27666 at 27689-693) or the SPF test method
223 described in the 2007 proposed rule (72 FR 49070 at 49114-119).

224 Such products should otherwise be labeled in compliance with the final rule and the
225 recommendations of this guidance, as applicable. We believe that this additional time
226 will be sufficient to permit testing of all formulations in compliance with the final rule
227 without creating disruption in supply.

228
229 We do not intend to exercise enforcement discretion for OTC sunscreen products initially
230 marketed prior to [INSERT DATE OF PUBLICATION OF FINAL RULE] if they are
231 labeled with an SPF that was generated by a method other than that included in the 2011
232 final rule, 1999 final rule, or 2007 proposed rule.

234 **D. Products That Claim to Have Specific SPF Values Higher Than 50**

235
236 This section describes how we intend to exercise our enforcement discretion with regard
237 to sunscreen products that claim to have specific SPF values higher than 50. In the 2007
238 proposed rule, we proposed that OTC sunscreen products with SPF values higher than 50
239 be labeled as “SPF 50+” or “SPF 50 plus.” In the 2011 proposed rule, we have retained
240 this proposal. However, we intend to continue to exercise enforcement discretion for
241 sunscreen products labeled with specific SPF values higher than 50 if those values are
242 determined according to SPF testing as described in Section C of this guidance, until we

¹¹ Specifically, the compliance date for all products subject to the final rule with annual sales less than \$25,000 is [INSERT DATE 2 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE], while the general compliance date for all other products subject to the rule is [INSERT DATE 1 YEAR AFTER DATE OF PUBLICATION OF FINAL RULE].

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243 issue a final rule based on the 2011 proposed rule. Therefore, sunscreen products that
244 claim to have specific SPF values higher than 50 should be:

- 245
- 246 • Tested to determine the SPF value as described in Section C of this guidance,
247 and
- 248 • Labeled in compliance with § 201.327 and § 310.545(a)(29)(ii), and the
249 recommendations of this guidance, as applicable.

E. Dosage Forms

251
252
253 In the 2011 ANPR on dosage forms of OTC sunscreen products, we listed the following
254 dosage forms as potentially eligible for inclusion in the OTC sunscreen monograph:

- 255 • oils
- 256 • lotions
- 257 • creams
- 258 • gels
- 259 • butters
- 260 • pastes
- 261 • ointments
- 262 • sticks
- 263 • sprays

264 During the pendency of rulemaking regarding these dosage forms, we do not intend to
265 initiate enforcement action for OTC sunscreen products formulated in any of the listed
266 dosage forms if they comply with the 2011 final rule or the recommendations of this
267 guidance, as applicable. As stated in the 2011 ANPR, we tentatively conclude that the
268 record is sufficient to support including these dosage forms, except for sprays, in the
269 future OTC sunscreen final monograph under the conditions of labeling and testing
270 included in new § 201.327. If we do not receive sufficient data for sprays in response to
271 the ANPR, we intend to propose that sprays not be included in a final sunscreen
272 monograph as a GRASE dosage form. Pending submission of the requested data that
273 would allow establishment of monograph conditions for sunscreens formulated as sprays,
274 we do not intend to object if manufacturers include the additional warning and directions
275 discussed in the 2011 ANPR, including the variation from the direction in
276 § 201.327(e)(1)(ii):

- 277 • Warnings:
 - 278 • **When using this product** keep away from face to avoid breathing it
- 279 • Directions:
 - 280 • spray liberally [*or generously*] and spread evenly by hand 15 minutes
281 before sun exposure (*This direction can be provided in lieu of that*
282 *described in § 201.327(e)(1)(ii.)*)
 - 283 • hold container 4 to 6 inches from the skin to apply
 - 284 • do not spray directly into face. Spray on hands then apply to face
 - 285 • do not apply in windy conditions
 - 286 • use in a well-ventilated area

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287
288 This labeling is intended to ensure that consumers use sunscreen sprays safely and
289 effectively.
290

291 The 2011 ANPR on dosage forms also raises certain questions regarding both broad
292 spectrum and SPF testing for sunscreen products in spray dosage forms. At the present
293 time, however, all sunscreen products covered by the final rule are subject to the testing
294 methods in § 201.327(i) and (j), regardless of dosage form. Therefore, while information
295 is being collected on testing methods for sunscreens formulated as sprays, sunscreens
296 formulated as sprays should be tested according to the rule and in light of the
297 recommendations regarding testing described in Sections III.B and C of this guidance.
298

299 The 2011 ANPR also listed those dosage forms that we did not consider currently eligible
300 for review for potential inclusion in the OTC sunscreen monograph:

- 301 • wipes
- 302 • towelettes
- 303 • powders
- 304 • body washes
- 305 • shampoos

306 OTC sunscreen products in these dosage forms are not currently eligible for review under
307 the OTC sunscreen monograph, because we lack the evidence that such products existed
308 in the OTC drug marketplace on or before May, 1972. OTC sunscreen products in these
309 dosage forms also have not established eligibility for review under the Time and Extent
310 Application (TEA) process (21 CFR 330.14(c)), because we have not received any TEAs
311 for these products. (That regulation specifies the process and content for establishing
312 eligibility for OTC drugs initially marketed in the United States after the OTC Drug
313 Review began in 1972, or with no U.S. marketing experience.) OTC sunscreen products
314 in these dosage forms that are marketed without an approved application therefore remain
315 liable to regulatory action unless and until the requirements of § 330.14(h) are satisfied.
316

317 Manufacturers of OTC sunscreen products in dosage forms that are not currently
318 considered eligible for the OTC Drug Review may submit the information needed to
319 support the eligibility of these products. In the 2011 ANPR, we invite submitters to
320 identify any additional sunscreen dosage forms that may be eligible for potential
321 inclusion in the OTC sunscreen monograph based on marketing prior to the
322 commencement of the OTC Drug Review in 1972. To establish such eligibility, a
323 manufacturer should submit actual product labeling or a facsimile of labeling that
324 documents the conditions of marketing prior to May 1972 (21 CFR 330.10(a)(2)).
325 Conditions include active ingredient, dosage form, dosage strength, route of
326 administration, and specific OTC use of the product (21 CFR 330.14(a)). Alternatively, a
327 manufacturer of an OTC sunscreen product in a dosage form that was not marketed in the
328 United States prior to the commencement of the OTC Drug Review in 1972 may submit a
329 TEA to support the potential inclusion of the condition in the OTC sunscreen monograph.
330 The requirements for establishing eligibility through a TEA are set forth in
331 21 CFR 330.14. If we determine that an OTC sunscreen product in any additional
332 dosage form is eligible for inclusion in the OTC sunscreen monograph, we would then

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333 publish a notice of eligibility requesting the submission of data to address its safety and
334 effectiveness. If these data support general recognition of sunscreens in this dosage form
335 as GRASE, we would include the condition in the OTC sunscreen monograph.
336

F. Insect Repellent-Sunscreen Combination Products

337
338
339
340 Some sunscreen products subject to § 201.327 also contain an insect repellent registered
341 by the EPA. Some of the labeling requirements in § 201.327 may conflict with EPA's
342 labeling requirements for insect repellents, as discussed in the 2007 ANPR. We have not
343 yet made a determination on these conflicts. We encourage manufacturers of these
344 products to comply with the labeling in § 201.327 as closely as possible.
345

G. OTC Sunscreen Products Not Covered By the Intended Enforcement Discretion

346
347
348 Not all OTC sunscreen products lacking approved applications fall within the intended
349 exercise of enforcement discretion described in this guidance. This includes products
350 marketed without an approved application that have any of the following characteristics:
351

- 352 • Contain active ingredients or combinations of active ingredients not included
353 in the list in Section II of this guidance (and previously included in
354 21 CFR 352.10 or 352.20, which are now stayed),
- 355 • Make claims that render a product misbranded or are not permitted on any
356 OTC sunscreen marketed without an approved application, according to
357 21 CFR 210.327(c)(3) and (g) and 310.545(a)(29)(ii),
- 358 • Are formulated in dosage forms that were not marketed prior to the inception
359 of the OTC Drug Review, or
- 360 • Contain an insect repellent ingredient that is not registered by EPA
361

362 In addition, OTC sunscreen products containing any active ingredients found eligible for
363 possible inclusion in the OTC sunscreen monograph under a TEA cannot be legally
364 marketed without an approved application unless and until we find the active ingredients
365 GRASE and other procedural requirements are satisfied (21 CFR 330.14(h)). Consistent
366 with this requirement, we do not intend to exercise enforcement discretion with respect to
367 an OTC sunscreen product marketed without an approved application if it contains any of
368 the following active ingredients found eligible for possible inclusion in the OTC
369 sunscreen monograph under TEAs: amiloxate, bemotrizinol, bisoctrizole, enzacamene,
370 diethylhexyl butamino triazone, octyl triazone, or ecamsule (68 FR 41386; 70 FR 2449;
371 71 FR 2405; 73 FR 53029). However, any OTC sunscreen product that does not fall
372 within our enforcement discretion (as defined in this guidance) or otherwise comply with
373 the requirements of the regulations may be marketed under a new drug application
374 approved under section 505 of the Act (21 U.S.C. 355).