

(c) Reasonable and necessary costs to maintain the breakthrough device.

(d) Related care and services for the breakthrough device.

(e) Reasonable and necessary services to treat complications arising from use of the breakthrough device.

#### **§ 405.607 Coverage period.**

(a) *Start of the period.* The MCIT pathway begins on the date the breakthrough device receives FDA market authorization.

(b) *End of the period.* The MCIT pathway for a breakthrough device ends as follows:

(1) No later than 4 years from the date the breakthrough device received FDA market authorization.

(2) Prior to 4 years if a manufacturer withdraws the breakthrough device from the MCIT pathway.

(3) Prior to 4 years if the breakthrough device becomes the subject of a national coverage determination or otherwise becomes noncovered through law or regulation.

Dated: May 4, 2020.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: June 11, 2020.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2020–19289 Filed 8–31–20; 8:45 am]

**BILLING CODE 4120–01–P**

## **DEPARTMENT OF THE INTERIOR**

### **Fish and Wildlife Service**

#### **50 CFR Part 17**

[FF09E21000 FXES11110900000 201]

#### **Endangered and Threatened Wildlife and Plants; Two Species Not Warranted for Listing as Endangered or Threatened Species**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of findings.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce 12-month findings on petitions to add Big Cypress epidendrum (*Epidendrum strobiliferum*) and Cape Sable orchid (*Trichocentrum undulatum*) to the List of Endangered and Threatened Plants under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best available scientific and commercial information, we find that it is not warranted at this time to list the Big Cypress epidendrum

or Cape Sable orchid. However, we ask the public to submit to us at any time any new information relevant to the status of either of the species mentioned above or their habitats.

**DATES:** The findings in this document were made on September 1, 2020.

**ADDRESSES:** Detailed descriptions of the basis for these findings are available on the internet at <http://www.regulations.gov> under the following docket numbers:

Species	Docket No.
Big Cypress epidendrum	FWS–R4–ES–2020–0043.
Cape Sable orchid .....	FWS–R4–ES–2020–0044.

Please submit any new information, materials, comments, or questions concerning this finding to the person specified under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** Roxanna Hinzman, Field Supervisor, U.S. Fish and Wildlife Service, South Florida Ecological Services Field Office, email: [roxanna\\_hinzman@fws.gov](mailto:roxanna_hinzman@fws.gov), telephone: 772–469–4309. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), we are required to make a finding whether or not a petitioned action is warranted within 12 months after receiving any petition that we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted (“12-month finding”). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted but precluded. We must publish a notice of these 12-month findings in the **Federal Register**.

##### **Summary of Information Pertaining to the Five Factors**

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife and Plants (Lists). The Act defines “species” as any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. The Act defines “endangered species” as any species that is in danger of extinction

throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and “threatened species” as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species’ continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term “threat” to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term “threat” includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term “threat” may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an “endangered species” or a “threatened species.” In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The

Secretary determines whether the species meets the definition of an “endangered species” or a “threatened species” only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term “foreseeable future,” which appears in the statutory definition of “threatened species.” Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term “foreseeable future” extends only so far into the future as the Service can reasonably determine that both the future threats and the species’ responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. “Reliable” does not mean “certain”; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species’ likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species’ biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

In considering whether a species may meet the definition of an endangered species or a threatened species because of any of the five factors, we must look beyond the mere exposure of the species to the stressor to determine whether the species responds to the stressor in a way that causes actual impacts to the species. If there is exposure to a stressor, but no response, or only a positive response, that stressor does not cause a species to meet the definition of an endangered species or a threatened species. If there is exposure and the species responds negatively, we determine whether that stressor drives or contributes to the risk of extinction of the species such that the species warrants listing as an endangered or threatened species. The mere identification of stressors that could affect a species negatively is not sufficient to compel a finding that listing is or remains warranted. For a species to be listed or remain listed, we require evidence that these stressors are

operative threats to the species and its habitat, either singly or in combination, to the point that the species meets the definition of an endangered or a threatened species under the Act.

In conducting our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether the Big Cypress epidendrum (*Epidendrum strobiliferum*) and Cape Sable orchid (*Trichocentrum undulatum*) meet the definition of “endangered species” or “threatened species,” we considered and thoroughly evaluated the best scientific and commercial information available regarding the past, present, and future stressors and threats. We reviewed the petitions, information available in our files, and other available published and unpublished information. These evaluations may include information from recognized experts; Federal, State, and tribal governments; academic institutions; foreign governments; private entities; and other members of the public.

The species assessment forms for the Big Cypress epidendrum and Cape Sable orchid contain more detailed biological information, a thorough analysis of the listing factors, and an explanation of why we determined that these species do not meet the definition of an endangered species or a threatened species. This supporting information can be found on the internet at <http://www.regulations.gov> under the appropriate docket number (see **ADDRESSES**, above). The following are informational summaries for each of the findings in this document.

#### *Previous Federal Actions*

On April 20, 2010, we received a petition from the Center for Biological Diversity, Alabama Rivers Alliance, Clinch Coalition, Dogwood Alliance, Gulf Restoration Network, Tennessee Forests Council, and West Virginia Highlands Conservancy to list 404 aquatic, riparian, and wetland species, including the Big Cypress epidendrum and Cape Sable orchid, as endangered or threatened species under the Act. On September 27, 2011, we published 90-day findings for both species in the **Federal Register** (76 FR 59836), concluding that the petition presented substantial information indicating that listing the Big Cypress epidendrum and Cape Sable orchid may be warranted. This document constitutes our 12-month findings on the April 20, 2010, petition to list the Big Cypress epidendrum and Cape Sable orchid under the Act.

#### *Big Cypress Epidendrum*

##### *Summary of Finding*

The Big Cypress epidendrum is an epiphytic, herbaceous plant with small white flowers in the Orchidaceae family. The species is found across the tropical Americas and the Caribbean, including in Collier County, Florida, United States, as well as in Mexico, Cuba, Dominica, Dominican Republic, Guadeloupe, Haiti, Jamaica, St. Vincent, Trinidad and Tobago, Guatemala, Belize, Honduras, Nicaragua, Costa Rica, Panama, Colombia, Ecuador, Peru, Bolivia, Brazil, French Guiana, Surinam, Guyana, and Venezuela. The best available data suggest that the species’ current range has not changed significantly from its historical range.

The Big Cypress epidendrum is a long-lived perennial with a typical orchid life cycle from seed to flowering plant. Mature Big Cypress epidendrum plants usually produce flowers in October and November, but they may flower at any time of the year; seed capsules have been observed on plants in March. All orchids produce capsules containing thousands of miniscule seeds that are dispersed by wind. The Big Cypress epidendrum can self-fertilize, but may also be pollinated by bees, flies, butterflies, and moths (Dressler 1990, p. 106; North American Orchid Conservation Center 2018).

For successful recruitment, the seed requires suitable host fungi to be present where they land. After successful germination on a suitable host tree, seedlings grow for several years before reaching maturity. The exact number of years to maturity is not known, but likely depends on resource availability (principally light and water). After approximately 10 years, adult plants may consist of many stems arising from leaf axils and the plant’s base. Individual plant lifespan is unknown, but is likely many years to decades, due to continuous vegetative generation of pseudo-bulbs (sympodial growth).

In Florida, Big Cypress epidendrum plants are found in dense tangles high on the branches or trunks of canopy trees and occasionally standing dead wood (snags) in habitats classified as wooded slough and strand swamp. Slough and strand swamp habitats are broad, shallow channels with peat over mineral substrate, which are seasonally inundated with flowing water.

Outside of the United States, the Big Cypress epidendrum occurs in tropical hammocks, tropical rain forests, and lowland rainforests, up to 4,500 feet (ft) (1,371 meters (m)) in elevation. In Brazil, the species has been recorded in the following vegetation types: Riverine

Forest and/or Gallery Forest, Inundated Forest, Terra Firme Forest, Seasonally Semideciduous Forest, Ombrophyllous Forest (Tropical Rain Forest), and Coastal Forest that are within the following biomes: Amazon Rainforest, Central Brazilian Savanna, and Atlantic Rainforest (Flora do Brasil 2020, entire).

Habitat elements that are important to the Big Cypress epidendrum include host trees with partial sun exposure in epiphytic microhabitats in swamps, rainforests, and cloud forests; nearly continual high humidity without freezing temperatures; and germinating seeds requiring the presence of symbiotic fungal species in order to grow to maturity.

The primary stressors affecting the Big Cypress epidendrum's biological status include habitat destruction and modification and hydrologic modification. Habitat destruction and modification are caused by changes in the host trees' forest structure occurring now and into the future through impacts from sea-level rise, such as salt water intrusion and inundation, and deforestation. However, the species' distribution and occurrences across a wide range (25 countries with at least 81 to 300 populations) within a variety of habitat types ensure that the Big Cypress epidendrum will not be in danger of extinction in the foreseeable future.

We carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Big Cypress epidendrum, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these stressors.

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. We identified a concentration of threats acting on the Florida portion of the species' range. Sea-level rise affects the Florida population disproportionately compared to the rest of the species' range due to the population's proximity to the coast and occurrence in low-elevation areas, and is expected to reduce the amount of suitable habitat for the host trees. However, as explained in our species assessment form (available on <http://www.regulations.gov> under Docket No. FWS-R4-ES-2020-0043), we found no substantial information to indicate that the Florida portion of the species' range is a biologically significant portion of the range. Accordingly, we find there is no significant portion of the range that is

endangered or likely to become endangered within the foreseeable future.

Our review of the best available scientific and commercial information indicates the Big Cypress epidendrum does not meet the definition of an endangered species or a threatened species in accordance with sections 3(6) and 3(20) of the Act. Therefore, we find that listing the Big Cypress epidendrum is not warranted at this time. A detailed discussion of the basis for this finding can be found in the Big Cypress epidendrum species assessment form and other supporting documents (see ADDRESSES, above).

#### *Cape Sable Orchid*

##### Summary of Finding

Cape Sable orchid is an epiphytic, lithophytic (growing on rock substrate), or sometimes terrestrial herbaceous plant that is found across the tropical Americas and the Caribbean, including in Monroe County, Florida, United States, as well as in Cuba, Mexico, Jamaica, Saint Vincent and the Grenadines, Trinidad and Tobago, Belize, Guatemala, Honduras, Nicaragua, Colombia, Ecuador, Peru, Venezuela, French Guiana, Surinam, Guyana, and Brazil. The best available data suggest that the species' current range has not changed significantly from its historical range.

The Cape Sable orchid is a long-lived perennial with a typical orchid life cycle from seed to flowering plant. Mature Cape Sable orchid plants usually produce flowers from April through October. All orchids produce capsules containing thousands of miniscule seeds that are dispersed by wind.

For successful recruitment, the seed requires a suitable host fungus to be present where it lands. After successful germination on a suitable host substrate, seedlings grow for several years before reaching maturity. For this species, the exact number of years to maturity is not known, but likely depends on resource availability (principally light and water). Adult plants may consist of many stems arising from leaf axils and the plant's base. The species' life span is unknown, but is likely many years, due to new outgrowths on the stem.

In Florida, the Cape Sable orchid occurs as an epiphyte on the branches or trunks of canopy trees and occasionally standing dead wood (snags) primarily in buttonwood hammock and, to a small extent, in mangrove forest habitat. The species historically occurred in coastal berm and rockland hammock habitat. The Cape Sable orchid has not been

observed growing on rock substrate in Florida.

Outside the United States, the Cape Sable orchid occurs in the understory of mesic hilly broadleaf forests, montane rain forests, and cloud forests, on tree trunks or rocks, or in leaf mold on limestone rocks at elevations from 30 to 3,100 ft (10 to 950 m).

Habitat elements that are important to the Cape Sable orchid include host trees with partial sun exposure in epiphytic microhabitats in swamps, rainforests, and cloud forests; nearly continual high humidity without freezing temperatures; and germinating seeds requiring the presence of symbiotic fungal species in order to grow to maturity.

The primary stressors affecting the Cape Sable orchid's biological status include habitat destruction and modification, hydrologic modification, insect damage, and poaching. Habitat destruction and modification are caused by changes in the host trees' forest structure occurring now and into the future through impacts from sea-level rise, such as salt water intrusion and inundation, and deforestation. The species' distribution and occurrences across a wide range (in 19 countries and 81 populations) within a variety of habitat types ensure that the Cape Sable orchid will not become in danger of extinction in the foreseeable future.

We carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Cape Sable orchid, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these stressors.

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. We identified a concentration of threats acting on the Florida portion of the species' range. Sea-level rise affects the Florida population disproportionately compared to the rest of the species' range due to the population's proximity to the coast and occurrence in low-elevation areas, and is expected to reduce the amount of suitable habitat for the host trees. However, as explained in our species assessment form (available on <http://www.regulations.gov> under Docket No. FWS-R4-ES-2020-0044), we found no substantial information to indicate that the Florida portion of the species' range is a biologically significant portion of the range. Accordingly, we find there is no significant portion of the range that is

endangered or likely to become endangered within the foreseeable future.

Our review of the best available scientific and commercial information indicates the Cape Sable orchid does not meet the definition of an endangered species or a threatened species in accordance with sections 3(6) and 3(20) of the Act. Therefore, we find that listing the Cape Sable orchid is not warranted at this time. A detailed discussion of the basis for this finding can be found in the Cape Sable orchid species assessment form and other supporting documents (see **ADDRESSES**, above).

#### *New Information*

We request that you submit any new information concerning the taxonomy

of, biology of, ecology of, status of, or stressors to the Big Cypress epidendrum or Cape Sable orchid to the person specified under **FOR FURTHER INFORMATION CONTACT**, whenever it becomes available. New information will help us monitor these species and make appropriate decisions about their conservation and status. We encourage local agencies and stakeholders to continue cooperative monitoring and conservation efforts.

#### **References Cited**

A list of the references cited in the petition finding are available on the internet at <http://www.regulations.gov> in the dockets provided above in **ADDRESSES** and upon request from the person specified under **FOR FURTHER INFORMATION CONTACT**.

#### **Authors**

The primary authors of this document are the staff members of the Species Assessment Team, Ecological Services Program.

#### **Authority**

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

#### **Aurelia Skipwith,**

*Director, U.S. Fish and Wildlife Service.*

[FR Doc. 2020–16721 Filed 8–31–20; 8:45 am]

**BILLING CODE 4333–15–P**