CLAIMS

1. A pharmaceutical composition comprising:

3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I;

a pharmaceutically acceptable carrier; and

an additional therapeutic agent selected from a mucolytic agent, bronchodialator, an anti-biotic, an anti-infective agent, an anti-inflammatory agent, a cystic fibrosis transmembrane conductance regulator (CFTR) modulator, or a nutritional agent,

wherein Form I is a crystal form having a monoclinic crystal system, a $P2_1/n$ space group, and the following unit cell dimensions:

a = 4.9626 (7) Å	α = 90°
b = 12.2994 (18) Å	β = 93.938 (9)°
c = 33.075 (4) Å	γ = 90°.

2. A pharmaceutical composition comprising:

3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I;

a pharmaceutically acceptable carrier; and

an additional therapeutic agent selected from a mucolytic agent, bronchodialator, an anti-biotic, an anti-infective agent, an anti-inflammatory agent, a cystic fibrosis transmembrane conductance regulator (CFTR) modulator, or a nutritional agent,

wherein Form I is characterized by one or more peaks 15.2 to 15.6 degrees, 16.1 to 16.5 degrees, and 14.3 to 14.7 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation at 40 kV, 35 mA.

3. The pharmaceutical composition according to claim 1 or 2, wherein the additional therapeutic agent is a CFTR modulator.

4. The pharmaceutical composition according to any of claims 1 to 3, wherein the CFTR modulator is N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide.

5. A pharmaceutical composition according to any of claims 1 to 4 for use in a method of treating cystic fibrosis.

6. Use of a pharmaceutical composition according to any of claims 1 to 4 in the manufacture of a medicament for treating cystic fibrosis.

7. 3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I,

for use in a method of treating cystic fibrosis in a mammal,

wherein an effective amount of Form I is to be administered to the mammal; and

wherein an additional therapeutic agent is also to be administered;

wherein Form I is as defined in claim 1 or 2.

8. 3-(6-(1-(2,2-Difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I for use as in claim 7, wherein the additional therapeutic agent is N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide.

9. 3-(6-(1-(2,2-Difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I for use as in claim 7 or claim 8, wherein Form I is to be administered concurrently with, prior to, or subsequent to the additional therapeutic agent.

10. N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide for use in a method of treating cystic fibrosis in a mammal,

wherein an effective amount of N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide is to be administered to the mammal; and

wherein an additional therapeutic agent which is 3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl) cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I is also to be administered;

wherein Form I is as defined in claim 1 or 2.

11. N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide for use as in claim 10, wherein Form I is to be administered concurrently with, prior to, or

subsequent to 3-(6-(1-(2,2-Difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I.

12. Use of 3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl) cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I in the manufacture of a medicament for use in a method of treating cystic fibrosis in a mammal,

wherein the medicament is prepared for administration to the mammal in an effective amount; and

wherein the medicament is prepared for administration with an additional therapeutic agent;

wherein Form I is as defined in claim 1 or 2.

13. Use according to claim 12, wherein the additional therapeutic agent is N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide.

14. Use according to claim 12 or claim 13, wherein the medicament is prepared for administration concurrently with, prior to, or subsequent to the additional therapeutic agent.

15. Use of N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide in the manufacture of a medicament for use in a method of treating cystic fibrosis in a mammal,

wherein the medicament is prepared for administration in an effective amount; and

wherein the medicament is prepared for administration with an additional therapeutic agent which is 3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I;

wherein Form I is as defined in claim 1 or 2.